

**GenIC Clearance for CDC/ATSDR
Formative Research and Tool Development**

Supporting Statement B

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

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B. Collections of Information Employing Statistical Methods

B.1. Respondent Universe and Sampling Methods

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 (birth control), and pregnancy with their healthcare providers, and examine provider comfort with and use of alcohol screening and brief intervention (SBI). The research results will be used to inform materials and messaging for patients and providers about alcohol use during pregnancy.

There are three components to this study: 1) Online survey of healthcare providers (physicians and nurse practitioners); 2) Individual in-depth interviews with healthcare providers; and 3) Individual in-depth interviews with women of reproductive age (21 – 45 years of age).

The sampling frame for the healthcare provider online survey and follow-up in-depth interviews will be physicians and nurse practitioners within the Dynata Healthcare Professional Panel who provide direct care to patients in a primary care setting such as family medicine, obstetrics/gynecology, preventive medicine, or internal medicine. The use of an online panel is driven by its ability to reach healthcare professionals from any part of the country in a timely and cost-efficient manner.

The sampling frame for individual in-depth interviews with women of reproductive age (21 to 45 years of age) will include women residing in any one of the 4 metropolitan areas: Atlanta, Georgia; New York, New York; Chicago, Illinois; and San Diego, California.

B.1.a. Respondent Universe of Healthcare Providers

According to Dynata'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 (Dynata – Healthcare Professionals Panel, 2015).

Dynata 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,

preventive 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.

B.1.b. Sampling Method for Health Care Providers

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.

Healthcare Provider Online Survey Inclusion Criteria:

Survey participants must meet the following inclusion criteria to participate in the online survey:

- Work as a physician or nurse practitioner.
- Provide direct patient care, including treatments, counseling, self-care, patient education, and administration of medicine. Participants may make administrative decisions for the clinic or perform other duties, but to be eligible, participants must provide direct care.
- Must work in one of the following specialties: internal medicine, general practice, family medicine, preventive medicine, or obstetrics/gynecology.
- Must either work in private practice or for a public provider (e.g., federally qualified health center, health department, community health center, Veterans Affairs, or the Indian Health Service). All other medical practice settings are ineligible.

Additionally, EurekaFacts will use screening questions to ensure that survey respondents meet the requirements of the study, including asking participants to identify whether they work in an urban or rural setting. EurekaFacts will monitor these criteria with an effort to interview participants from both settings.

The online survey will allow for the examination of patterns and relationships as they relate to reported behaviors, attitudes, and experiences of healthcare providers who care for women of reproductive age. The topics for the survey were selected based on a thorough literature review which identified gaps in knowledge about alcohol SBI and FASDs. The survey will include items to assess provider receptivity to messaging, materials and factors influencing the effective adoption of alcohol SBI to prevent fetal alcohol spectrum disorders (FASD). Some survey items aim to identify barriers that affect dissemination strategies of alcohol SBI and any institutional or structural barriers that may affect its implementation. Other questions ask about practice type and collect zip code geographic data of practice location to understand participant characteristics. The relationship between these items, such as practice characteristics, perceived salience of the issue of FASD among the patient population, and challenges related to patient-provider interactions around alcohol, pregnancy and contraception, will be examined. The target sample size for online panel survey completions is 500.

Together, the online survey and in-depth interviews (described below) will provide rich information on provider beliefs, attitudes, and cultural frames informing alcohol use; provider views on delivering services to women of reproductive age, and provider perceptions of self-efficacy and comfort delivering alcohol SBI and counseling patients. These data will support the development of appropriate messaging to help motivate providers to include alcohol SBI in their practice, build self-efficacy in delivering alcohol SBI, and allow for the development of tailored communication materials for healthcare providers based on their current motivations and practices in delivering alcohol SBI.

Healthcare Provider Individual In-Depth Interview Recruitment:

Individual in-depth interview participants will be recruited by EurekaFacts via email requests to respondents who completed the online healthcare provider survey who are identified as physicians or nurse practitioners, providing direct care to patients in primary care settings, specializing in internal medicine, preventive medicine, family medicine, or obstetrics/gynecology, and who provide consent to share their contact information and participate in follow-up in-depth interviews.

Provider In-depth Interview Inclusion Criteria:

In order to participate in individual in-depth interviews, healthcare providers must consent to be interviewed following the completion of the online survey. Among these respondents, participants will be selected based on reported alcohol SBI practice behaviors, with assigned quotas for each group:

- Healthcare providers who currently deliver alcohol SBI.
- Healthcare providers who formerly delivered alcohol SBI, but no longer do so.
- Healthcare providers who have never delivered alcohol SBI.

Additionally, EurekaFacts will use screening questions to ensure that survey respondents meet the requirements of the study, including asking participants to identify: profession, primary medical specialty, whether or not they provide direct patient care, type of practice (private or public), and whether they work in an urban or rural setting. EurekaFacts will monitor these criteria with an effort to interview participants from both settings. Participants for the healthcare provider in-depth interviews will be identified based on their answer to a survey question regarding their utilization of alcohol SBI. No additional screening for provider interviews will be necessary, although there will be questions at the start of the interview to confirm that they are in the correct alcohol SBI utilization group. The target sample size for healthcare provider individual in-depth interviews is 36. Total participants will be assigned to three groups with quotas for (1) 15 providers currently delivering alcohol SBI, (2) 15 providers who formerly delivered alcohol SBI, and (3) 6 providers who have never delivered alcohol SBI.

The individual in-depth interviews will provide further understanding of providers' receptivity to and use of professional communication materials about risky alcohol use and alcohol SBI. This information will also provide insight as to whether new materials or new dissemination strategies are needed to address challenges and barriers to delivery of alcohol SBI. The research team will also identify common themes in providers' receptivity to materials. Specifically, the focus of the qualitative analysis will be to inform how CDC can best disseminate information about alcohol SBI, including additional information needs and outreach strategies to improve the effectiveness of messaging on alcohol SBI and FASDs.

B.1.c. Respondent Universe of Women of Reproductive Age

For the third component of the study, individual in-depth interviews with women of reproductive age (21 – 45 years of age), readily available quantitative data on the respondent universe for the study population help to frame the sampling and analysis choices. The 2016 Census indicates there are roughly 51 million women between the ages of 21 and 44 years old in the United States (Ruggles, et al. 2017). Using the overall average fertility rate for women within this age group, approximately 3.6 million women are within the study's target population age range and gave birth in 2016. A little over half (53.6%) of non-pregnant women reported drinking alcohol in the previous 30 days, according to Behavioral Risk Factor Surveillance System data, and 10.2% of pregnant women aged 18 to 44 reported drinking alcohol in the past 30 days (Tan et al., 2015). Of the pregnant women who reported alcohol use in the past 30 days, use was highest among women ages 35 to 44 years, college graduates, and unmarried women.

The study population will include women of reproductive age (21 – 45 years of age) and have representation from the following groups of women:

- Women who have never been pregnant, are not trying to get pregnant, but are sexually active and have consumed alcohol in the past 3 years.
- Women who have never been pregnant and are trying to get pregnant and have consumed alcohol in the past 3 years.
- Women who have had a baby in the previous year and have consumed alcohol in the past 3 years.

As noted above, data collection for this component, targeting women of childbearing age, will employ the qualitative method of in-depth interviewing, not intended to yield results that can be generalized to the overall population. Therefore, results from this research will not be used to make statements representative of the universe of study, to produce statistical descriptions, or to generalize findings beyond the scope of the sample.

B.1.d Sampling Method for Women of Reproductive Age

The study sample of women of reproductive age (21 – 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; New York, NY; Atlanta, GA; and San Diego, CA. These cities were selected based upon their internal demographic and socio-economic diversity and their geographic diversity from one another.

Women of Reproductive Age In-depth Interview Recruitment:

The EurekaFacts team will recruit a sufficient number of participants to complete 72 interviews with women of reproductive age. Respondents will be recruited to achieve a mix of age, race/ethnicity, education, socioeconomic background across all 72 interviews.

In order to meet the sample requirements outlined above and maximize effectiveness of the recruitment, EurekaFacts will utilize a multi-pronged recruitment approach which will include three main methods: 1) recruitment using the EurekaFacts Panel in existing markets that correspond with the desired geographical regions, 2) general advertisement method, and 3) individual/direct recruitment with multiple modes such as individual emails and telephone recruiting. Specific methods and resources will be used to recruit participants, as follows:

1. EurekaFacts panel recruitment: Contact female members of the database of individuals and households in the desired geographic location, offering a brief

online screener to promote interest and participation. Please see **Attachment H** for the text of the online screener and **Attachment I** for associated screenshots.

2. General advertisements method: Use of classified advertisements or more general announcements to appear in online and print versions of local newspapers and news websites. Please see **Attachment G** for recruitment materials.
3. Direct recruitment via multiple contact methods: Email and phone recruitment efforts utilizing emails and phone contact lists available from a highly reputable commercial vendor that provides similar direct marketing outreach services for major national corporations and consumer brands. Referrals from personal networks at the time of responding to general appeals and after completing interviews will be pursued.

In addition, to maximize the effectiveness of recruitment and data collection, EurekaFacts will carefully design screening questions that identify the characteristics of interest (e.g. age, gender, race and ethnicity, regions, alcohol consumption, relationship status, etc.), family status (had a baby in the year prior, intent to have children or not), and at minimum, contact information including first name, phone number, email address, and zip code. The screener will establish targets for demographic groupings based on age, race and ethnicity, and education level by regions.

The recruitment plan will address strategies for ensuring that recruiting procedures are implemented as consistently as possible across all entities involved in recruiting. This will involve project-specific training of the recruitment staff, consistent screening procedures across all locations and recruiting organizations, and use of such tools as programmed online screeners, and Interview Progress Tracking tool among other tracking resources together with daily or more frequent communication between EurekaFacts and each of the recruiting locations.

Potential participants who have initially qualified via online screener will be further screened using a pre-approved screener script and questionnaire to be programmed into a computer-assisted telephone interviewing (CATI)-like software (Verint) to ensure that the screening procedure is uniformly conducted, instantly quantifiable throughout the recruitment

effort, and that qualified and screened individuals who fit the criteria are then scheduled for an interview. The interviewer will send out a confirmation email and letter that includes the date, time, and interview location, along with a map, directions, and any other information that may be required. Interviewees will receive a telephone reminder at least 24 hours prior to their appointment to confirm participation as well as to field any questions they may have regarding their participation. If participants opt to receive text messages, a text message will be sent to remind them of their appointment on the day of the scheduled interview.

Women of Reproductive Age In-depth Interview Inclusion Criteria:

Participants will be selected for inclusion and ultimately recruited to meet specific required quotas for each of three primary groups as determined by pregnancy intention, sexual activity, and alcohol consumption. Specifically, participants in each geographic location will be stratified into three groups:

- Women who have never been pregnant, are not trying to get pregnant, but are sexually active and have consumed alcohol in the past 3 years.
- Women who have never been pregnant and are trying to get pregnant and have consumed alcohol in the past 3 years.
- Women who have had a baby in the previous year and have consumed alcohol in the past 3 years

EurekaFacts anticipates screening 300 women to obtain 72 respondents. All interviews will be conducted only one time. The results of the individual in-depth interviews with women of reproductive age will be used to inform materials and messaging for patients and providers about alcohol use and pregnancy. Qualitative methods provide flexible in-depth exploration of the participants' perceptions and experience, and the interviews yield descriptions in the participants' own words. Qualitative methods also allow the interviewer flexibility to pursue relevant and important issues as they arise during the discussion. Furthermore, a qualitative approach will allow the researcher to capture subtle nuances in participants' attitudes, beliefs, and feelings related to the issue of pregnancy and alcohol use. In-depth interview guides include

probes to ensure that input on specific items of interest is obtained while open-ended questions ensure that participants' responses and perceptions are fully addressed and captured.

B.2. Procedures for the Collection of Information

B.2.a. Healthcare Providers

For the healthcare provider online survey and individual in-depth interviews, providers will be recruited from the Dynata Healthcare Provider Panel. The healthcare provider panel includes a variety of specialties, including but not limited to the following: cardiovascular disease, endocrinology, family practice, neurology, obstetrics and gynecology, and thoracic surgery. Dynata maintains the Health Care Professionals Panel with approximately 65,000 actively practicing healthcare physicians and 2,200 nurse practitioners. Provider panelists are recruited through a multi-mode invitation approach to maximize coverage and response using a combination of email, fax and phone. Panel participants are verified with the American Medical Association and local associations to ensure data reliability.

The healthcare panel participants who meet the eligibility criteria will receive an invitation to complete an online survey from Dynata. EurekaFacts uses the online Vovici survey programming platform to program, invite, implement and receive case-level data from the Dynata Panel. Dynata will not directly handle or manage any of the final deliverables for the study. In the data collection process, Dynata provides unique IDs to all panelists to secure their identity and provides EurekaFacts with potential respondents who fit the predefined sample study criteria. A final dataset will be downloaded from the Vovici platform on a secure server to the EurekaFacts worksite location.

Participants will encounter informed consent (**Attachment A**) at the beginning of the online survey and must choose the option indicating their consent to proceed with the online survey. The participants will then encounter the screening questions which will determine their eligibility for participation in the online survey. These screening questions will reflect the sampling frame described above. If the participant meets the necessary eligibility criteria, respondents will continue on to the online survey. The online survey will take approximately 15 minutes to complete. At the end of the survey, there will be several questions asking if the participant would consent to participate in a follow up in-depth interview, and if so, to provide

their contact information. A separate informed consent statement will be required prior to completing an in-depth interview. This verbal consent is found as **Attachment B**.

The final online survey sample will include a mix of physicians and nurse practitioners, as well as different levels of usage of alcohol SBI. Data collection and sample composition will be closely monitored to achieve a sample that satisfies the defined criteria: both physicians and nurse practitioners with different levels of alcohol SBI use to ensure that meaningful comparisons among those groups can be analyzed. The absence of an estimated incidence of alcohol SBI use among healthcare professionals makes it difficult to confidently set reachable quotas for physicians and nurse practitioners for their level of alcohol SBI use.

Healthcare provider in-depth interview respondents will be drawn from among the survey participants who consent to be interviewed. Participants to be interviewed will be selected based on how well they meet the alcohol SBI segmentation criteria outlined above. All respondents will be preregistered active participants of the online healthcare provider survey. EurekaFacts will recruit participants for the individual in-depth interviews via phone. The phone interview, which will be recorded, will commence when the healthcare provider verbally indicates their consent to participate. The interview will be 30 minutes and will be recorded.

Dynata will distribute survey and in-depth interview incentives to the participants who complete the survey and who complete the in-depth interview. Dynata, a commercial online panel provider, will manage the healthcare provider online survey and identify participants for the in-depths provider interviews. Using an online provider panel is an efficient and cost-effective way to get access to healthcare providers. The costs of recruiting and interviewing providers based on a list sample would be beyond the resources available for this effort. Dynata uses a point system for their panel participants which then translates into dollars once the participants redeem the points. The cash equivalent that healthcare providers will receive for participating in this data collection effort are: \$10 for completion of the online survey and \$100 for the individual in-depth interviews. The incentive amounts commonly offered to healthcare provider are between \$125-175 for a 30-minute interview. Incentives are used, in a non-coercive manner for multiple federal data collection efforts, including the National Health and Nutrition Examination Survey and the National Survey of Family Growth (Bureau of Labor Statistics,

2015). Healthcare providers are typically offered more in order to gain cooperation and ensure a robust sample from this population which is harder to reach than the general public. Provision of incentives to healthcare providers will also help maximize the response rate for this data collection request.

B.2.b. Women of Reproductive Age

For the individual in-depth interviews with women of reproductive age, EurekaFacts will recruit study participants in each of the four study sites (Chicago, IL; New York, NY; Atlanta, GA; and San Diego, CA). Interviewers will use a screener (**Attachment H**; please see **Attachment I** for associated screenshots) to identify eligible participants. As participants are recruited for the individual in-depth interviews, recruitment grids will be used track and coordinate recruitment. The recruitment grids will list participants' first names, some demographic information obtained from the screener, and if the woman is trying to get pregnant, not trying to get pregnant, or has had a baby in the prior year. The grids will not contain any personal identifying information. The recruitment grids will be stored in a locked file cabinet or on a password-protected project share drive at the EurekaFacts worksite. Paper copies of the recruitment grids will be destroyed at site locations after data collection is completed. EurekaFacts will maintain copies of the recruitment grids for the purpose of technical reporting on the study sample. These copies of the recruitment grids will be kept in locked file cabinets or on a password-protected project shared drive at EurekaFacts and AIR for the duration of the study.

Recruitment will begin at least 4 weeks before the individual in-depth interviews are scheduled. EurekaFacts will keep AIR and CDC apprised of recruitment progress and make adjustments if needed. Identification of recruitment facilities and recruitment will begin once Institutional Review Board (IRB) and Office of Management and Budget (OMB) clearances are received. Every effort will be made to schedule interviews at locations convenient for consumer participants, in order to reduce respondent burden, maximize participation rates, and accommodate busy schedules among female consumers. Dates will be assigned to each activity on the timeline for tracking and monitoring purposes after receiving IRB and OMB clearances.

Personal identifying information from potential participants responding to individual in-depth interviews will be maintained and protected to the extent allowable by law. The screeners will be kept in locked file cabinets or on secure servers maintained and monitored by EurekaFacts. All identifying information (name, address, telephone number) will be recorded on the last page of the screener, which will be used to provide reminder letters/e-mails and make reminder phone calls to prospective participants. The last page of the screener will be torn off and destroyed after the individual in-depth interviews are conducted. Once the project ends, the screeners will be destroyed. No identifying information about participants will be kept after the study is completed.

Reminder letters/e-mails for the individual in-depth interviews will be sent to potential participants prior to the data collection, giving them directions to the study site and a copy of the informed consent form (**Attachment C**) to review prior to the interview. Confirmation calls or e-mails will also be made 1 to 2 days prior to the in-depth interviews to ensure that all recruits are confirmed.

Once the potential participant comes to the study site and checks in for the individual in-depth interview, she will be given an opportunity to ask any questions if she has not already signed the informed consent form. If the participant agrees to be in the study, she will provide consent. The participant will be given a copy of the informed consent form to keep for her records, and then data collection will proceed. The interview guides are found as **Attachment K**.

All participants will be reminded that they can refuse to answer any question and they can stop their participation in the study at any time without penalty. EurekaFacts staff will mail or personally take all forms back to their worksite after the interviews are completed in field locations. The consent forms will be stored in a locked file cabinet at the EurekaFacts worksite for the duration of the project. Once the project ends, all forms will be destroyed.

Each data collection for the individual in-depth interviews with women of reproductive age will last a total of 60 minutes. The individual in-depth interviews will be audio-recorded for the purpose of completing the final reports. All audio recordings will be destroyed after notes have been verified and no links will be maintained to any data collected.

EurekaFacts anticipates compensating women of reproductive age with a \$40 gift card for their participation in a 60 minute interview. These incentives will be provided by EurekaFacts interviewers upon completion of the in-person interview. The incentive amounts commonly offered to participants from the general public fall between \$20 and \$50. These 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.

B.3. Methods to Maximize Response Rates and Deal with Non-Response

B.3.a. Healthcare provider survey and interviews

Healthcare providers will be recruited from a multi-mode invitation approach to maximize coverage and response rates using a combination of email, fax and phone. Online survey panelists will receive email reminders through the Vovici platform to complete surveys.

Considering that an online panel will be used to field this survey, a non-response bias analysis per se cannot be conducted. But when key characteristics of the study population are available and clearly defined for the overall target population, a comparison of their distribution among the panel of respondents to their distribution in the study population can be made. In that case, post-stratification weighting can be used to ensure that the distribution of panel respondents on those characteristics, hypothesized to influence the outcome being studied, match the target population's marginal distribution on the same characteristics.

Individual in-depth interview respondents will be drawn from those healthcare providers who have already taken the online survey. The interviews will be short (about 30 minutes) and conducted by telephone at a time convenient for the respondent. Reminder e-mails will be sent to participants scheduled for the provider interviews to remind them of the time of the interviews. In addition, incentives provided by Dynata will be used to boost response rates.

B.3.b. Interviews with Women of Reproductive Age

The following procedures will be used for the individual in-depth interviews among women of reproductive age to maximize cooperation and achieve the desired participation rates:

- EurekaFacts professional recruitment staff will recruit participants.
- Reminder letters/e-mails will be sent to participants with directions to the research site and reminder phone calls placed 1 to 2 days prior to the scheduled data collection. Participants will not be contacted again after the in-depth interviews are over.
- A token of appreciation will be provided to thank participants for their time and participation in the study

B.4. Test of Procedures or Methods to Be Undertaken

To estimate the burden for administering the screening questionnaire for women of reproductive age, EurekaFacts consulted two different project team members. The project team members tested the online screening survey for clarity, flow, and skip patterns. The project team members estimated the maximum average burden for the screening instrument to be 5 minutes. The screening instrument is shown in **Attachment H**, with screenshot in **Attachment I**. The screening interview instruments will not be pilot tested with members of the public, but extensively reviewed by researchers experienced in conducting qualitative data collection tasks. The in-depth interview guides can be found in **Attachment K**.

Similarly, the online healthcare provider survey, which includes screening questions for healthcare providers, was tested by multiple team members for length of time for survey burden, as well as clarity, flow, and skip patterns to ensure that it would conform to the target of 15 minutes. The survey instrument is shown in **Attachment D** with screenshots in **Attachment E**. The timing for the in-depth interview for healthcare providers was determined by experienced qualitative interviewers based on their previous experience. The in-depth interview instrument is shown in **Attachment F**.

B.5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The individuals consulted on technical and statistical issues related to data collection are listed below. The data will be collected by EurekaFacts and analyzed by the both EurekaFacts and American Institutes for Research.

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