Safer Use of Medications During Pregnancy

NCBDDD Generic Information Collection Request

OMB No. 0920-0990

**Supporting Statement – Section B**

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**Section B – Collections of Information Employing Statistical Methods**

1. **Respondent Universe and Sampling Methods**

Six virtual focus groups and a follow-up telephone interview will be conducted with women of childbearing age (18-44) via the Internet rather than in person. The virtual focus groups are targeted to one of six audience segments. Table 1 presents the proposed audience segmentation scheme.

Table 1: Focus Group Segmentation (n = 6 focus groups)

|  |  |  |
| --- | --- | --- |
| **Respondents** | **Medication Status** | **Number of Focus Groups** |
| Women age 18-44 planning to become pregnant in next 1–2 years who . . . | Currently take prescription pain medication for chronic pain | 1 |
| Currently take a prescription antidepressant | 1 |
| Currently use a prescription asthma medication | 1 |
| Women age 18-44 who had a baby within the last year who . . | Took a short term medication for a condition that arose during previous pregnancy | 1 |
| Took a prescription antidepressant during pregnancy | 1 |
| Used a prescription asthma medication during pregnancy | 1 |
| **TOTAL** |  | **6 groups** |

The data collection will not use statistical methods to select respondents. We will use a professional recruitment firm to recruit participants for these focus groups. RTI will work with Manthan Panels, a recruitment and marketing research agency that has proven success in recruiting participants. The recruiter will use the questionnaire to screen and assign participants to groups. The recruiter will recruit a maximum of 24 participants per group, resulting in an actual group size of no more than 12 participants.

1. **Procedures for the Collection of Information**

To conduct the virtual focus groups, we will partner with an online focus group vendor, Itracks, using a live chat platform. We will host the group as a real-time, live chat session, which allows the moderator to post questions and probes and allows participants to type responses visible to the moderator and all other participants. These groups will last approximately 60–90 minutes and involve up to 12 participants in each group. A trained RTI moderator will lead the group and use a semi-structured moderator guide to ask questions, probe for details, and lead participants in an open discussion.

During the virtual groups with consumers, the RTI team will observe participants and select those who offer compelling or noteworthy experiences and responses for follow-up interviews Participants will be selected based on these criteria:

* Actively engaged in virtual focus group;
* Shared experiences related to struggling with a decision to continue/start medication during pregnancy;
* Responded that they rely on more than one source of information for medication use during preconception/pregnancy;
* Provided a detailed response to the message testing questions.

The RTI team will ask participants from each consumer group if they wish to participate in a follow-up telephone interview to describe their responses in more detail and provide additional information about their experiences. RTI will select two participants from each group, for a total of 12 participants based on the following criteria:

* Actively engaged in virtual focus group;
* Shared experiences related to struggling with a decision to continue/start medication during pregnancy;
* Responded that they rely on more than one source of information for medication use during preconception/pregnancy;
* Provided a detailed response to the message testing questions.

Follow-up interviews will be semi-structured, and designed to go more in-depth to specific experiences and narratives related to factors that affect decision-making about medication use during pregnancy. The follow-up interviews will take 30 minutes and will be moderated by a trained RTI team member. Interviews will be audio-recorded and professionally transcribed. RTI team members will independently review and code transcripts from the virtual groups and the interviews in NVivo 10.0 qualitative analysis software. Team members will examine participants’ responses and code responses based on a predetermined coding structure. Once coding is complete, we will produce coding reports and identify trends across the groups and, when applicable, within the group segments. The RTI analysis team will review transcripts and then analyze them using the following steps (adapted from Krueger & Casey, 2000):

1. Assign each focus group an identification number.

2. Code the responses according to a set of predeveloped codes that represent key constructs.

3. Develop and assign emergent codes for responses that do not fit the preexisting coding scheme.

4. Using these pre-established and emergent codes, identify the key themes and determine the degree of consensus or discordance with a particular view; the goal of a focus group is to focus on what the group thinks, not on what the individual thinks.

5. In a cross-group matrix, organize the key themes in accordance with the research question most closely addressed by the group, noting particularly relevant quotes.

6. Using the cross-group matrix, identify cross-cutting themes and areas lacking consensus.

The steps described above are designed to systematically summarize responses from the individual to the group level and then to the cross-group level in an objective and transparent manner. RTI will ensure that the data are coded consistently and objectively by double-coding a sample of transcripts. RTI will seek the input of CDC technical officers in interpreting the data (steps 4 and 6) to further enhance the objectivity of the analytic process.

1. **Methods to Maximize Response Rates and Deal with No Response**

To maximize participation and achieve the desired participation rates we will use the following procedures:

* We will over recruit for the groups. Manthan Panels recommends recruiting 24 participants/group to achieve a show rate of 12 participants/group for each virtual focus group.
* Manthan Panels will send a confirmation letter at the time of scheduling, as well as reminder e-mails and phone calls in the days leading up to each group. They have successfully used these methods to achieve high show rates in many studies.
* A standard incentive will be provided to the participants for their time and effort (see Section A-9).

1. **Test of Procedures or Methods to be Undertaken**

The data collection guides have been reviewed by CDC staff and pilot tested with 3 or fewer RTI personnel.

1. **Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data**

Data collection and analysis will be performed by RTI personnel. We anticipate the data to be straightforward and not require complex analysis techniques.

The interviewers and primary data analysts consist of the following RTI personnel:

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