Information Collection #1:

Perceptions of Health Risk from Smokeless Tobacco Products and Nicotine Replacement Therapy among Pregnant Women and Women Planning a Pregnancy

Submitted for approval under CDC generic approval #**0920-0910**
Message Testing for Tobacco Communication Activities

June 25, 2013

Data Collection Instruments

- Attachment 1a. Screener (Pregnant Women)
- Attachment 1b. Screener (Non-pregnant Women)
- Attachment 2a. Moderator's Guide: Women's Perceptions of Tobacco Products (Pregnant Women)
- Attachment 2b. Moderator's Guide: Women's Perceptions of Tobacco Products (Non-pregnant Women)
- Attachment 3. Informed Consent

Attachments

- Attachment 4a-b. RTI Institutional Review Board Approval
- Attachment 5. Recruitment Firm Nondisclosure Agreement
- Attachment 6a-c. Educational materials for distribution at conclusion of sessions
- Attachment 7. Tobacco product information

Section B: Statistical Methods

B.1 Respondent Universe and Sampling Methods

This is a descriptive and exploratory qualitative research project. Statistical methods will not be used to select respondents. The study design calls for a total of 18 focus groups and up to 16 in-depth interviews (IDI) four per city as needed. This design is necessary to capture potential differences in respondents' perceptions that may be attributable to geographic regions. Table 1 describes our recruitment strategy. Our aim is to include eight respondents for each focus group for a total of 144 respondents. Given concerns about last minute cancellations, 12 women will be recruited for each focus group (i.e., 9 respondents and 3 alternates). Based on recruitment findings from our pilot test with a minimal number of individuals (< 9), we will give pregnant smokers the option to participate in a one-on-one IDI instead of a group setting focus group should they prefer to do so. We anticipate that 1 out 3 women contacted will meet the eligibility criteria and agree to participate. Therefore, we anticipate that 36 women will be contacted and screened for *each* focus group in order to recruit 12 for participation and ensure 8 actual focus group participants. This suggests that a total of 648 women (i.e., 18 focus groups x 36 women) will be contacted and screened using the Screener (Attachment 1). IDI participants

will be recruited from same pool of screened women and no additional women will be contacted and screened for IDIs.

Table 1. Recruitment Strategy

	5 Focus Groups	5 Focus Groups	4 Focus Groups	4 Focus Groups
	City 1	**City 2**	**City 3**	**City 4**
Pregnant	Smokers Children *(*English Speaking Hispanic)*	Smokers No Children *(**Spanish Speaking)*	Smokers Children	Smokers Children
	Quitters Children	Quitters Children	Smokers No Children	
	Quitters No Children	Quitters No Children	Quitters No Children	Quitters Children
NonPregnant	Smokers Children *(*English Speaking Hispanic)*	Smokers Children	Smokers Children	Smokers Children
	Smokers No Children	Smokers No Children *(**Spanish Speaking)*		Smokers No Children

We will obtain a convenience sample of potential women participants from recruitment lists managed by focus group facilities in the cities described below. Potential participants will be contacted by telephone and their interest and eligibility for participation in the study will be evaluated using the Screener (Attachments 1a and 1b). Eligible respondents will be pregnant women who are smokers or who quit after they became pregnant and women who currently smoke who are planning to become pregnant. Women who stopped smoking after they became pregnant must have stopped smoking for more than 30 days. Two groups will be conducted in Spanish with Hispanic women and two groups will be conducted with English-speaking Hispanic women. Participants will be screened and may be selected based on the following eligibility criteria.

- Inclusion Criteria
  - Age 18-40
  - Currently pregnant or planning to get pregnant in the next year
  - Is a current smoker OR
  - Quit smoking after becoming pregnant
- Exclusion Criteria

- 17 or younger, 41 or older
- Not pregnant or not planning to be pregnant in the next year
- Currently smokes less than once a week
- Stopped smoking before becoming pregnant
- Stopped smoking less than 30 days ago
- Worked for a tobacco company, marketing agency, or anti-tobacco organization
- Has ever lobbied for tobacco related issues
- Attended a health-related focus group in the past 6 months

Focus groups and IDIs will be conducted in-person at professional focus group facilities in four cities in different quadrants of the United States. Facilities will be selected based on the prevalence of smokeless tobacco products in these markets and prevalence of smoking during pregnancy and the demographics of these cities. The proposed sites include

- Manchester, New Hampshire
- Oklahoma City, Oklahoma
- Billings, Montana
- Lexington, Kentucky

B.2 Procedures for the Collection of Information

The data collection contractor, RTI International, will be responsible for coordinating data collection activities with professional focus group facilities, collecting and summarizing information, and preparing reports. RTI will subcontract with focus group facilities to recruit for 18 focus groups and IDIs as needed. The focus group facility will screen and recruit participants according to the screener and the segmentation strategy via telephone. The focus group facility will confirm participant availability 1 week before the focus group and remind participants of the date and time of their focus group/IDI via telephone 1 to 2 days beforehand.

The focus groups and IDIs will be conducted in person at focus group facilities by a professionally trained RTI moderator. Each focus group will last no longer than ninety minutes and each IDI will last no longer than 1 hour. RTI staff will attend the focus groups and IDIs to take notes on a laptop computer and coordinate logistics of checking in participants and obtaining informed consent. All focus groups will be audio and video recorded. IDIs will be audio recorded as well. A professional transcriptionist will prepare verbatim transcriptions without identifiers of all focus groups.

As noted earlier, we will recruit 12 participants for each focus group to ensure 8 participants. Consequently, if more than eight of those recruited arrive at the focus group facility, the first eight will be asked to participate and the others will be paid the $75 monetary gift and excused from participation. Some pregnant smokers may opt to participate in an IDI instead of a focus group but the total number of women recruited will remain constant (i.e., if four women choose an IDI over the focus group, the number of women recruited for the focus group will be reduced by four).

RTI will explain the study and ask participants to sign an informed consent form if they agree to participate prior to attending the focus group or IDI (see Attachments 2a and 2b). RTI staff will explain the process and distribute and collect the consent forms. Before each group or IDI, the moderator will review the consent form with the participants to ensure that they understand their rights and to ensure they are participating voluntarily.

The consent forms will be printed in duplicate, with one copy retained by RTI and the other copy provided to the project participants. The consent forms retained by RTI will be stored in a locked filing cabinet at RTI. Only select project staff will have access to the project files. Focus group and IDI participants will receive $75 at the conclusion of the focus group or IDI as an appreciation for participation.

At the end of the groups, RTI will provide educational materials; including the Clearing the Air booklet (for all groups) and postcard advertising the national tobacco quit line (tailored specifically for women who are pregnant).

B.3 Methods to Maximize Response Rates and Deal with Nonresponse

The recruitment plan includes a gift of $75 to promote efficient enrollment in this voluntary study.

B.4 Test of Procedures or Methods to be Undertaken

The proposed project is formative in nature and involves the collection of qualitative information. The data collection instruments have been piloted.

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

There are no statistical aspects of this project, but the individuals collecting and/or analyzing data are listed below.

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