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 4 a-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 A: Justification for Information Collection

A.1 Circumstances Making the Collection of Information Necessary

Cigarette smoking during pregnancy is known to increase the risk of adverse pregnancy outcomes. Although exposure to cigarette smoke presents risks for all smokers (e.g., cancer, pulmonary disease), there are additional risks for women who smoke during pregnancy and for their fetuses. Several studies have shown that smoking during pregnancy is associated with perinatal complications, including preterm delivery, placental abruption, placenta previa, and fetal growth restriction (Andres & Day, 2000). Additionally, secondhand smoke can increase an infant's risk of SIDS, respiratory tract infections (e.g., bronchitis and pneumonia), and ear infections (CDC, 2001, 2004, 2006 in Tong et al., 2009). Furthermore, from 2000 to 2004, an estimated 776 infants died annually from causes attributed to maternal smoking during pregnancy (CDC, 2008 in Tong et al., 2009).

In recent years, manufacturers of tobacco products have invested heavily in a new generation of smokeless tobacco products that encompass a wide range of products. It has been suggested that using smokeless tobacco products is safer than smoking cigarettes because smokeless tobacco use does not

result in exposure to products of combustion (Asplund, 2001; Rodu, 2006). Researchers suggest that adults may perceive dissolvables to be less harmful than cigarettes (Kim & Zhang, 2011; McClave et al., 2010). In a national sample, McClave and colleagues (2010) found that 39.3% of respondents believed dissolvables to be less harmful than cigarettes. Among Florida adult smokers, Kim and Zhang (2011) found that 22.6% perceived dissolvables to be less harmful than cigarettes and 37.6% reported not knowing the relative risk.

Although the prevalence of smokeless tobacco use in women is currently low in the United States, more research is needed to better understand perceptions of harm for smokeless tobacco products and how these beliefs compare to nicotine replacement therapy (NRT), how they may vary by subgroups, and how they may be predictive of use. Because pregnant women and women intending to become pregnant are often highly motivated to protect the health of their fetuses, these women may be especially attuned to smokeless tobacco products and marketing that expressly state or imply reduced harm. Therefore, knowing how smokeless products and NRT are viewed by pregnant women and women intending to become pregnant merits attention in order to help shape public health messages, intervention and policy strategies to prevent smokeless tobacco use in pregnant women and women of reproductive age.

Privacy Impact Assessment Information

Overview of the Information Collection

The objective of the proposed research is to assess, via focus groups and in-depth interviews (IDIs), the awareness, attitudes, and perceptions, particularly health risk perceptions of smokeless tobacco products and NRT to self and to fetus, of pregnant women and women of childbearing age (18 to 40 years) who are planning or trying to become pregnant in the next year. Focus groups will be conducted with pregnant women who are smokers or who quit after they became pregnant and women who currently smoke who are planning to become pregnant. 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 in-depth interview (IDI) instead of a group setting focus group should they prefer to do so.

Women who stopped smoking after they became pregnant must have stopped smoking for more than 30 days. We also examine factors that might influence this population to change products (especially from cigarettes to smokeless tobacco products) and/or resume tobacco use with a new product.

Data collection for this effort will consist of a total of eighteen 90 minute focus groups and up to four 60 minute IDIs per city (16 total) on an as needed basis (up to 4 per city) contingent on participant preference. The focus groups and IDIs will take place in four cities. Proposed cities are Manchester, NH; Oklahoma City, OK; Billings, MT; and Lexington, KY although the locations may be subject to change due to logistical (e.g., change in availability of recruiting firms) or technical issues (e.g., increased or decreased tobacco sales).

Items of Information to be Collected

To determine eligibility for the study, a professional recruitment firm will collect information about participants, including age, pregnancy status, smoking status, potential conflicts to participation,

education level, race/ethnicity, and preferred language. For a full list of items, please see the screener (Attachments 1a and 1b).

Attachments 2a and 2b contain the moderator's guide for the focus groups and IDIs. RTI International will conduct the focus groups and IDIs and will store resulting data for three years after the completion of the project. Discussion questions will focus on smoking status and behaviors; awareness, use, and reactions to emerging smokeless tobacco products; risk perceptions of these new products; and awareness of, use, and reactions to nicotine replacement therapy (NRT).

Notes, discussion transcripts, and questionnaires from the focus groups and IDIs will not be in an identifiable form. However, the recruitment firms in each city will collect limited information in identifiable form (IIF) through the screener (Attachments 1a and 1b) in order to categorize participants according to the audience segments.

The number of questions will be held to the absolute minimum required for the intended use of the data.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

All respondents will be 18 years of age or older. There is no website content directed at children younger than 13 years of age.

A.2 Purpose and Use of Information Collection

The information to be collected will allow CDC to assess awareness, attitudes, and perceptions--particularly health risk perceptions of smokeless tobacco products and NRT to self and to fetus--of pregnant women and women of childbearing age (18 to 40 years) who are planning or trying to become pregnant in the next year. This information will be used to inform the development of public health message concepts and communication strategies regarding smokeless tobacco use and reproductive health. If this data collection is not performed, CDC will not know how to develop messages that credibly and effectively educate women across these audience segments.

CDC and FDA will use this information to better understand how these target groups respond to marketing messages related to smokeless tobacco products and NRT. Ultimately, this information will be used to develop educational messages to help women make informed decisions about use of these products before and during pregnancy.

A.3 Use of Improved Information Technology and Burden Reduction

Due to the nature and scope of this project, incorporating improved information technology (e.g. web-based technology) for the purpose of data collection is not feasible. Upon consent from the participants, we will audio and video record the discussions to capture all information and assist with the preparation of reports. The use of electronic reporting is typically not feasible for this form of qualitative work.

A.4 Efforts to Identify Duplication and Use of Similar Information

Prior to conducting any data collection, CDC reviews existing published literature on a bi-weekly basis and unpublished qualitative pretesting reports when they are available, and also consults with outside experts to identify information that could facilitate future message development based on the formative qualitative findings from this data collection. Health messages developed by CDC are unique in their mix of intended audience, health behavior, concept, and execution. Therefore, there are no similar data available.

CDC/OSH collaborates with other U.S. government agencies that sponsor health communication projects such as the U.S. Food and Drug Administration's (FDA) Center for Tobacco Products. These affiliations serve as information channels and help prevent redundancy. Ongoing communication, including bi-weekly meetings between CDC's Office of Smoking and Health and FDA's Center for Tobacco Products, as well as other federal agencies ensures that information collections are coordinated and not duplicative.

A.5 Impact on Small Business or Other Small Entities

There will be no impact on small businesses or other small entities.

A.6 Consequences of Collecting the Information Less Frequently

This is a one-time request; therefore, it is not possible to ask participants to participate in the focus groups or IDIs less frequently.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The testing activities fully comply with the regulation and guidelines in 5 **CFR 1320.5.** There are no special circumstances.

A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

CDC and FDA collaborated on the development of this information collection, including design of the overall message testing activity as well as the design of specific instruments. Our collaborator at FDA is

Greta Tessman, MA
Food and Drug Administration
301-796-6722
Greta.Tessman@fda.hhs.gov

A.9 Explanation of Any Payments or Gift to Respondents

We will give participants in the focus groups and IDIs a monetary gift to show appreciation for their participation. Given this study targets a specific population (i.e., pregnant smokers), the recruiting firm may need to expand their efforts beyond their standard geographic recruitment area. Because many of these participants will have to travel, and in some cases longer than average distances, the gift may serve to offset costs related to traveling to the focus group/IDI facility. Many participants will also

have children, and the gift may also serve to offset childcare costs related to participating in the study. The amount is $75.00 for participation in a 90 minute focus group or 60 minute IDI.

This proposed gift of $75.00/participant is intended to recognize the time burden placed on the participants, travel and childcare costs, encourage their cooperation, and to convey appreciation for contributing to this important activity. Numerous empirical studies have shown that a monetary gift can significantly increase response rates (e.g., Abreu & Winters, 1999; Shettle & Mooney, 1999; Greenbaum, 2000).

The primary firm that will recruit the women for the focus groups and IDIs, Schlesinger Associates, Inc., recommends a minimum gift of $75 per participant for this hard to reach population. In their experience, they find a drop off in respondent commitment with any lower amount. In response to offering this level, respondents are much more likely to honor their commitment of participating in the focus group/IDI. Lower amounts could actually result in higher recruiting costs due to the need to over recruit by higher percentages (Krueger & Casey, 2009). Additionally, the focus groups will last not more than 1.5 hours and IDIs one hour.

A.10 Assurance of Confidentiality Provided to Respondents

Privacy Act Determination. Respondents will be recruited from an existing panel maintained by the data collection contractor (i.e., focus group/IDI facility). Although demographic information (e.g., gender, age, and race) will be gathered, no direct personal identifiers (e.g., full name, phone number, social security number, etc.) will be collected or maintained as part of the Screener (**Attachments 1a and 1b**), or Focus Group or IDI (**Attachments 2a and 2b**). No directly identifying information will be transmitted to CDC. The Privacy Act does not apply. Focus group facility staff who have contact with the respondents are required to sign a nondisclosure agreement to help ensure the respondent's privacy. Please see Attachment 5 for the Recruitment Firm Nondisclosure Agreement.

Safeguards. CDC and RTI will take many precautions to secure participants' identifiable information (see Privacy section of Consent Forms – Attachment 3). The information participants provide during the focus groups and IDIs will not be linked to their identities. Participants will use only first names or pseudonyms during the discussions. Transcripts and notes will not include participants' names. Audio files of the groups will be stored by RTI on a secure share drive and password-protected computers. Transcripts and reports will not include any identifiable information.

Identifying information (name, address, telephone number) will be used by the professional recruitment firm to make contact and send reminder calls to respondents. This information will be kept by the recruiting firm separately from any information collected in the groups. Screeners will be kept in a locked file cabinet at the recruitment firm or in password-protected computer files. The recruiter will only provide RTI and CDC a summary of participant information on the recruitment grids, which will be stripped of identifiable information, such as the last names, addresses, and telephone numbers of the participants. The professional recruiting firm will be instructed to destroy their project-related records at the conclusion of the project.

The precautions taken by CDC and RTI have been evaluated by the Institutional Review Board of RTI and found to be acceptable (see RTI IRB approval – Attachment 4).

Respondent Advisements and Consent. Respondents will be advised of the nature of the activity, the length of time it will require, and that participation is purely voluntary. Please see the Informed Consent Form (Attachment 3). Respondents will be assured that they will incur no penalties if they wish not to respond to the information collection as a whole or to any specific questions. These procedures conform to ethical practices for collecting data from human participants.

A.11 Justification for Sensitive Questions

The majority of questions asked will not be of a sensitive nature. There will be no requests for a respondent's Social Security Number (SSN).

It will be necessary to ask some questions considered to be of a sensitive nature in order to assess individuals' attitudes and behaviors, such as tobacco use during pregnancy. Questions about messages concerning smoking behavior (e.g., tobacco use) and some demographic information (e.g., race or ethnicity) could be considered sensitive, although these items would not generally be considered highly sensitive. A subset of questions about sensitive issues are necessary for audience segmentation and to collect information integral to the purpose of this study.

Sensitive information will only be requested when necessary for specific project objectives and steps to avoid negative reactions will be taken, including:

- Participants will be informed that they need not answer any question that makes them feel uncomfortable or that they simply do not wish to answer.
- Questions included in these focus groups and IDIs were pilot-tested with a minimal number of individuals (< 9) matching the characteristics of the target audience.

A.12 Estimates of Annualized Burden Hours and Costs

Screening of the audience with up to 648 women (396 pregnant women and 252 women smokers planning a pregnancy) will be conducted to determine qualification status for participating in the research.

Eighteen focus groups and up to 16 IDIs will be conducted with up to 144 women (88 pregnant women and 56 women smokers planning a pregnancy).

The estimated burden to respondents is 5 minutes for screening and no more than 90 minutes for a focus group. The total estimated burden for all responses is 270 hours. We assumed labor hours for all participants attending focus groups. *If pregnant smokers (up to 16 women) opt to conduct an IDI instead of a focus group, the burden hours would decrease. The reduction would range from one to 16 hours depending upon the number of women who opt to conduct an IDI.*

Table A.12.A. Estimated Annualized Burden to Respondents

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Pregnant Women (18-40) who smoke or who quit after becoming pregnant	Screener (Pregnant Women)	396	1	5/60	33
	Moderator's Guide: Women's Perceptions of Tobacco Products (Pregnant Women)	88	1	90/60	132
Non-pregnant women (18-40) smokers planning a pregnancy	Screener (Nonpregnant Women)	252	1	5/60	21
	Moderator's Guide: Women's Perceptions of Tobacco Products (Nonpregnant Women)	56	1	90/60	84
				Total	**270**

The estimated cost of the time devoted to this information collection by respondents is $6,210 as summarized in Table A.12.B. To calculate this cost, we used the mean hourly wage of $23, which represents the DOL estimated mean for state, local, and private industry earnings (U.S. Bureau of Labor Statistics, 2013). There are no direct costs to respondents associated with participation in this information collection.

Table A.12.B Estimated Annualized Cost to Respondents

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Average Hourly Wage	Total Burden Hours	Total Cost
Pregnant Women (18-40) who smoke or who quit after becoming pregnant	Screener (Pregnant Women)	396	1	$23	33	$759
	Moderator's Guide: Women's Perceptions of Tobacco Products (Pregnant Women)	88	1	$23	132	$3,036
Non-pregnant women (18-40) smokers planning a pregnancy	Screener (Nonpregnant Women)	252	1	$23	21	$483
	Moderator's Guide: Women's Perceptions of Tobacco Products (Nonpregnant Women)	56	1	$23	84	$1,932
Total						$6,210

A.13 Estimates of Other Annual Cost Burden to Respondents and Record Keepers

None.

A.14 Annualized Cost to the Federal Government

Approximately 18% each of 2 full time equivalents (FTE) will be required to oversee the information collection activities. Responsibilities will include internal coordination and review of materials and reports and maintaining proper accounting of burden hours. The agency estimates that it will take a GS-14, at a wage rate of $48.41/hour, approximately 335 hours/annually to manage the project, totaling about $16,217. It is estimated to take a GS-13, at a wage rate of $46.43 an hour, approximately 327 hours annually to assist in managing the project, totaling $15,182.

The total average annualized cost to the government for CDC oversight is $31,376

Government Personnel	Time Commitment	Hourly Basic Rate	Total
GS-14 step 1	18.17%	$48.41	$16,217
GS-13 step 5	17.0%	$46.43	$15,159
Total			$31,376

The majority of data collection activities will be conducted by contractors on CDC's behalf. The total cost of the data collection contractors is $338,981, which includes consultation, instrument design and development, recruitment, data collection, analyses, and reporting.

The grand total cost for the project, including government and contractor cost, is $370,357.

A.15 Explanation for Program Changes or Adjustments

This is a new data collection.

A.16 Plans for Tabulation and Publication and Project Time Schedule

The information will be used to inform health communication data across OSH. Information collection and analysis will occur from October 2013 – February 2014. Multiple steps are required between approval of this package and the launch in order to meet that target date. We have provided timeline scenarios for each of the data collection activities. Our target approval is July 2013, but assuming an OMB approval date no later than September 1, 2013, we plan to begin the information collection activity by November 1, 2013.

Activity	Date
Information Collection Form Submitted to OMB for approval (appx.)	6/30/2013
CDC receives OMB approval on Information Collection # 1	9/1/2013
Recruitment	9/2-10/31/13
Information Collection Activity Focus Groups and IDIs	11/1-2/1/14
Interim results to OSH	2/28/14
Final Reporting to OSH	4/31/14

Data analysis will include systematic analyses of the qualitative data to identify common themes, new or emergent themes, and any exceptions to these themes and to identify similarities and differences among the various subpopulations included in the study. The team will use qualitative analysis software, QSR NVivo to code and segment data according to a predetermined set of codes.

A.17 Reason(s) Display of OMB Expiration is Inappropriate

The expiration date of OMB approval will be displayed on all information collection instruments.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions are requested.

References

Abreu, D.A., & Winters, F. (1999). Using monetary incentives to reduce attrition in the survey of income and program participation. *Proceedings of the Survey Research Methods Section of the American Statistical Association*.

Andres, R. L., & Day, M. C. (2000). Perinatal complications associated with maternal tobacco use. *Seminars in Neonatology*, *5*(3), 231–241.

Asplund, K. (2001). Snuff—how dangerous is it? The controversy continues. *Journal of Internal Medicine*, *250*(6), 457–461.

Centers for Disease Control and Prevention (CDC). (2008). Smoking prevalence among women of reproductive age—United States, 2006. *Morbidity and Mortality Weekly Report*, *57*(31), 849–852.

Greenbaum, T. L. (2000). *Moderating focus groups: A practical guide for group facilitation*. Thousand Oaks, CA: Sage Publications, Inc.

Kim, A. E., & Zhang, T. (2011). *Results from the Tobacco Industry Monitoring Online Smokers' Survey*. Prepared for the Florida Bureau of Tobacco Prevention Program.

Krueger, R.A., Casey, M.A. (2009). *Focus groups: A practical guide for applied research*. (4th Ed.). Thousand Oaks, CA: Sage Publications, Inc.

McClave, A. K., Arrazola, R., & Dube, S. R. (2010). A national assessment of new and emerging tobacco products in the U.S. American Public Health Association. Retrieved from http://apha.confex.com/apha/138am/webprogram/Paper215071.html.

Rodu, B. (2006). Tobacco harm reduction: An alternative cessation strategy for inveterate smokers. *Harm Reduction Journal*, *3*, 37.

Shettle, C., & Mooney, G. (1999). Monetary incentives in U.S. government surveys. *Journal of Official Statistics*, *15*, 231-250.

Tong, V. T., Jones, J. R., Dietz, P.M., D'Angelo, D., & Bombard, J.M. (2009). Trends in smoking before, during, and after pregnancy—Pregnancy Risk Assessment Monitoring System (PRAMS), United States, 31 Sites, 2000–2005. *Morbidity and Mortality Weekly Report*, *58*(SS-4), 1–31.

U.S. Bureau of Labor Statistics. (2013). Average hourly and weekly earnings of all employees on private nonfarm payrolls by industry sector, seasonally adjusted. Accessed May 22, 2013 from http://www.bls.gov/news.release/empsit.t19.htm