Experimental Study of Graphic Cigarette Warning Labels

B. Statistical Methods

1. Respondent Universe and Sampling Methods

The respondent universe for the experimental study is (1) current smokers aged 25 years old and older, (2) young adult smokers aged 18 to 24 years old, and (3) youth aged 13 to 17 years old who smoke or may be susceptible to initiation of smoking. The three separate quota samples will be selected from the E-Rewards online member panel, a national opt-in email list sample. Sampled panel members will receive an email inviting them to participate in the study. Panel members who choose to participate will complete the questionnaire (see Appendix). Completed interviews will be monitored to ensure samples are diverse in terms of age, gender, education, and ethnicity/race. We estimate 13,500 respondents (or 4,500 respondents per sample) will complete a survey regarding warning labels on cigarette packs and an additional 4,500 respondents from group (1), i.e. current smokers aged 25 years and older, will complete a survey regarding warning labels within an advertisement.

The agency does not intend to generate nationally representative results or precise estimates of population parameters from the experimental study; generating a representative sample of the size necessary for this study, using Random Digital Dialing (RDD) or other similar method, would be cost prohibitive. The study will use convenience samples rather than probability samples. Despite the attempt to match between the study's sample and the respondent universe in four demographic characteristics, matching is used solely to produce a sample with a reasonable degree of diversity in key demographic characteristics.

2. Procedures for the Collection of Information

For the information collection, E-Rewards will send email invitations to the target audiences using their market research panel. Each invitation will contain the survey title, the length of the survey, incentive amount provided for successful completion of the survey, and instructions for accessing the secure website for the survey. Once a panel member enters the secure web site, a brief introduction will be presented informing the panel member of the confidential and voluntary nature of the survey (see Appendix). Individuals who consent to participate in the survey will be able to access the survey by clicking on the link to the survey URL. Respondents who access the questionnaire will be randomly assigned to an experimental condition.

This experimental study will be conducted using an Internet panel and a questionnaire designed to measure responses to the images and collect demographic and smoking status information from the participant. Participants will view a cigarette pack of a hypothetical brand of cigarettes which will contain a warning statement as well as an image intended to illustrate the warning statement. RTI will analyze information collected from the study, the results of which

will inform FDA's implementation of mandatory graphic warnings as required by the Tobacco Control Act.

The proposed design implements the experimental study with each of three target groups: (1) current smokers aged 25 or older, (2) young adult smokers aged 18 to 25, and (3) youth aged 13 to 17 who smoke or may be susceptible to initiation of smoking. In the experiment, we are testing 4 images on a cigarette package and 1 control condition (no image) for each of the 9 warning labels for a total of 45 cells. We will start with 100 smokers in each cell for a baseline sample size of 4500 for each of the three survey samples. If time allows, FDA will conduct a follow-up survey at 1 week with those who complete the baseline survey within the first week data collection. Assuming 50 respondents per cell respond within the first week of the baseline survey, and a 20% attrition for the follow-up survey, we anticipate n = 40 per cell or 1,800 total at 1-week follow-up.

Summary of protocol.

Baseline survey:

- Survey screener – confirm eligibility.
- Random assignment to treatment or control.
- Treatment groups are exposed to pack with warning statement and image; Control groups are exposed to pack with warning statement without image.
- Respondents provide information post exposure about recall of warning statement and image, emotional and cognitive reactions to warnings, beliefs about health risks of smoking and secondhand smoke, quit intentions and quit behaviors, susceptibility to smoking (youth), etc.

Survey of additional adult sample viewing smoking ad

- Since the new warning statements and images will be required to be placed on all advertisements for cigarettes, we will also test in the adult sample the effect of the labels on adult responses to a cigarette advertisement. The protocol for this additional sample will be the same as for the baseline survey described above with the exception that the respondents will view a mock cigarette advertisement (print ad). The treatment groups will see the ad with the new warning statement and image while the control group will view the print ad with a warning statement.
- The survey will be modified in this sample to ask about reactions to and recall of the print ad.
- There will be no 1-week follow-up of this sample

Follow-up survey at 1-week:

- Respondents provide information about recall of warning statement and/or image.

Measures

Key Outcomes (measured post exposure and/or at 1-week follow-up):

- Recall of the warning statements (aided)
- Recall of the images (aided)
- Cognitive and emotional reactions to the warning statements and labels
- Beliefs about the health risks of smoking and secondhand smoke
- Quit intentions
- Quit behaviors
- Openness to smoking (youth)
- Recall of the print ad (adult sample viewing print ad)
- Cognitive and emotional reactions to the print ad (adult sample viewing print ad)

Covariates and controls:

Age, gender, race, SES (income and education), smoking and quit history

Analysis plan

Tests:

1. Tests of treatment effect: comparison of outcomes in treatment group to control (note: control group will view pack with warning statement placed on pack similarly to current warnings). *Note: outcomes for tests measured post-exposure and/or at 1-week follow-up. Tests will be conducted unadjusted and then also adjusted for covariates/controls.*

Hypotheses:

- A greater proportion of respondents in treatment groups will recall the warning statements and/or images at follow-up than respondents in control groups.
- Respondents in treatment groups will report more intense emotional and cognitive reactions to packages and advertisement than those in control groups.
- Those in treatment groups will be more likely to recall information about the risks of smoking than those in control groups.

- Youth in treatment groups will report attitudes than indicate reduced openness to smoking than those in the control groups.

- A greater proportion of respondents in the treatment groups will report intentions to quit in the next 30 days

2. Contrasts between treatment groups: comparison of warning statements images to ascertain relative effectiveness. *Note: outcomes for tests measured post-exposure and/or at 1-week follow-up. Tests will be conducted unadjusted and then also adjusted for covariates/controls.*

- For each outcome listed in previous section, contrasts will be made between treatment groups (adjusted for multiple comparisons) to determine which graphic image had the largest effect relative to the control.

The sample design is adequately powered to test the primary research hypothesis:

- The outcome (e.g., perception of risk) for the groups viewing an image will be significantly different from the outcome for the group viewing no image.

Taking perception of risk as an example, perception can be measured either on a scale (0–100) or as a binary variable (0/1). We assume a sample size of 4,500 (100 observations for each warning by image condition). For the 0–100 scale outcome, we run a generalized linear model, unadjusted for covariates, and can detect a 1.6 point difference between perceived risk from the control group and the perceived risk from the image groups with 80% power. For the binary outcome, we run a logistic regression model, unadjusted for covariates, and can detect a 4.8% difference between the control and the images with 80% power. If the sample size were reduced to 1,980 (44 observations for each warning by image condition instead of 100), then the minimum detectable difference to test our primary hypothesis would increase to 2.4 points and 8% at 80% power. This power analysis also applies to examples of measures that employ Likert scale ratings, as these measures will be dichotomized prior to analysis, e.g., assigning high ratings a value of 1 and low ratings a value of 0.

Unusual Problems Requiring Specialized Sampling Procedures

No specialized sampling procedures are involved.

Use of Periodic Data Collection Cycles to Reduce Burden

This is a one-time survey data collection effort.

3. Methods to Maximize Response Rates

Experience with online experimental studies suggests that about 15% of those who are sent survey invitations will complete a study. FDA will implement several procedures to maximize participation. We will conduct cognitive interviews and pretests to help improve understandability of the questionnaire, to reduce participant burden, and to enhance interview

administration. We will keep the study questionnaire at a reasonable length to minimize break-offs. Additionally, the following procedures will be used to maximize cooperation and to achieve the desired response rates:

- A brief introductory paragraph will identify FDA as the sponsor of the study, state the purpose of the study, and encourage participation.
- E-Rewards will provide toll-free telephone numbers to all sampled individuals and invite them to call with any questions or concerns about any aspect of the study. RTI will provide a toll-free telephone number for a RTI project member and a toll-free telephone number for the RTI IRB hotline should participants have any questions about the study or their rights as a study participant.
- E-Rewards data collection staff will work with RTI project staff to address any problems that arise throughout the course of the collection of information.
- Nonrespondents will receive one e-mail reminder from E-Rewards requesting their participation in the survey.

4. Tests of Procedures or Methods

In August 2010, RTI will conduct 9 cognitive interviews with nine adult smokers to evaluate and refine the draft questionnaire (see Appendix A). The cognitive interviews will help identify areas where the instrument was ambiguous, burdensome, or confusing for respondents and the survey will be revised accordingly.

Additionally, we will conduct a pretest with individuals who are Federal employees to thoroughly test the programmed questionnaire. At the conclusion of the pretest, all strategies, algorithms, and programs for sampling, survey administration and data compilation will be tested, validated, and readied for launch of the Internet experimental survey. The questionnaire will be revised based on the pretest findings.

5. Individuals Involved in Statistical Consultation and Information Collection

RTI International will manage the information collection on behalf of FDA. James Nonnemaker is the project director at RTI. RTI will subcontract to e-Rewards to collect the data. Bethany Moffett is the project manager at e-Rewards. Analysis and dissemination of the data will be led by Conrad Choiniere at FDA's Center for Tobacco Products.

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