U.S. Food and Drug Administration
Formative Research Support: Outcomes and Awareness Measurement Research

OMB Control Number 0910-0810

SUPPORTING STATEMENT B

B. Statistical Methods

1. Respondent Universe and Sampling Methods

The respondent universe for this study is youth aged 13 to 17 years who are able to watch and hear videos on their electronic device (computer, tablet, or phone). The screener survey will include questions assessing race, ethnicity, gender identity, and state of residence. To ensure a reasonably diverse sample, we will set the following soft quotas:

- Maximum 70% female gender identity
- Maximum 85% white, non-Hispanic
- Approximately equivalent distribution across geographic regions

The study will use convenience samples rather than probability samples. We do not intend to generate nationally representative results or precise estimates of population parameters from the study; generating a representative sample of the size necessary for this study (e.g., using random digital dialing or a similar method) would be cost prohibitive. Additionally, it is not necessary as this is a measures development study.

2. Procedures for the Collection of Information

This section provides an overview of the study procedures, provides information on the degree of accuracy required for the study, and discusses the estimation procedures.

2a. ***Study Procedures***

Objectives and Research Questions

This study includes the following key objectives and research questions:

1) Objective: Examine the extent to which the distribution and accuracy of self-reported awareness varies across different awareness assessment approaches

- RQ1: To what extent does campaign awareness vary by awareness assessment approach?
- RQ2: Which awareness assessment approach is most valid?
- RQ3: Which awareness assessment approach is most sensitive to variation in campaign exposure?

2) Objective: Develop comprehensive, valid, multi-item scales to measure outcomes such

as addiction perceptions, expectations of feeling anxious after using tobacco, and other key predictors of tobacco use that campaign messages aim to change.

- RQ4: What is the factor structure and reliability of the scales?
- RQ5: Do the scales relate to other measures of the same construct and/or outcomes that the scales are hypothesized to be related to?

Study Design and Protocol

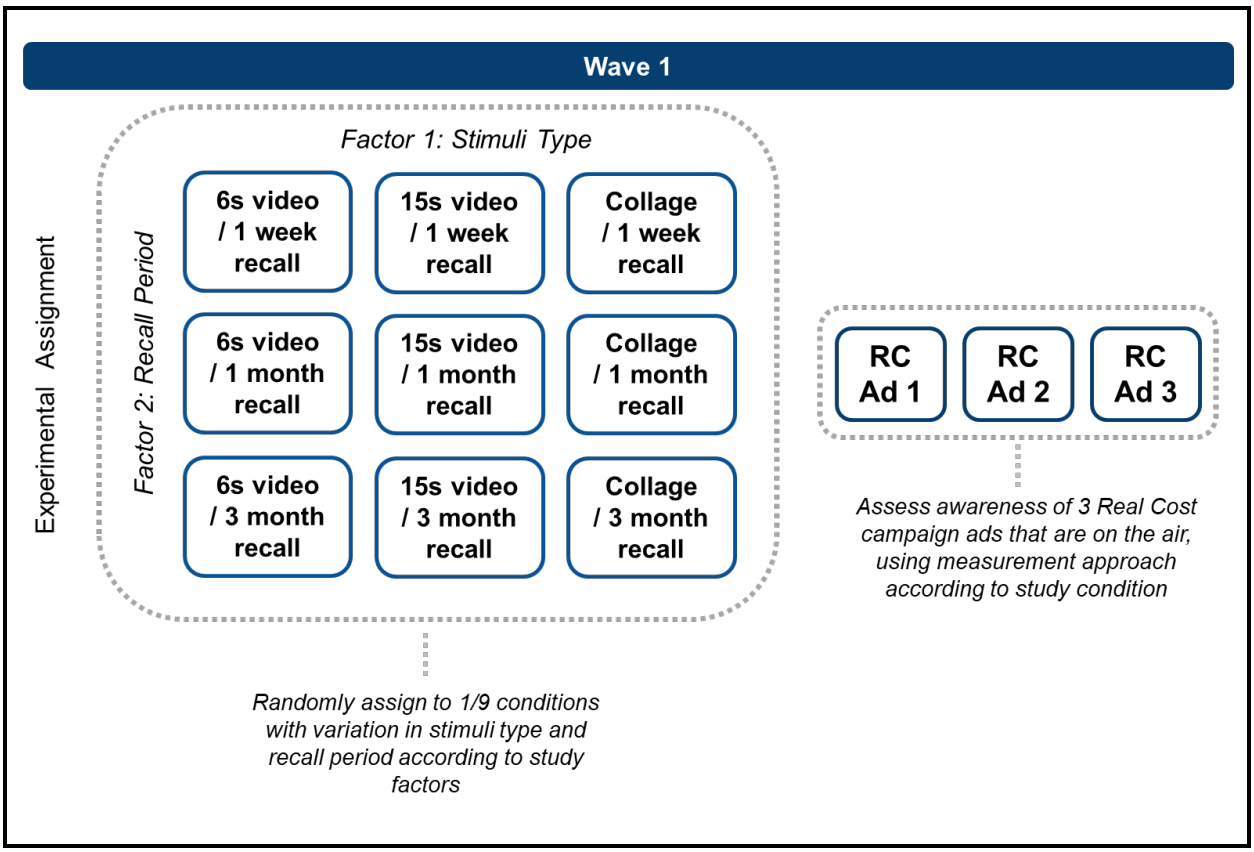
To address the objectives and research questions above, we will conduct a multicomponent study that includes two waves of data collection. The study will be administered via online surveys conducted among youth (aged 13-17), recruited from adult participants of a national online panel who are parents of a child in the eligible age range. The Wave 1 survey will be conducted among a sample of 2,400 youth, and Wave 2 will be conducted approximately 1-2 weeks later among youth from Wave 1 who agree to participate in the follow-up survey.

The study will include the following key components:

1) In Wave 1, we will administer a battery of attitudinal and belief items that campaign messages aim to change, to facilitate the development and assessment of multi-item scales for use in media campaign evaluation (Objective 2). These items will be asked again in Wave 2 to facilitate an analysis of test-retest reliability.

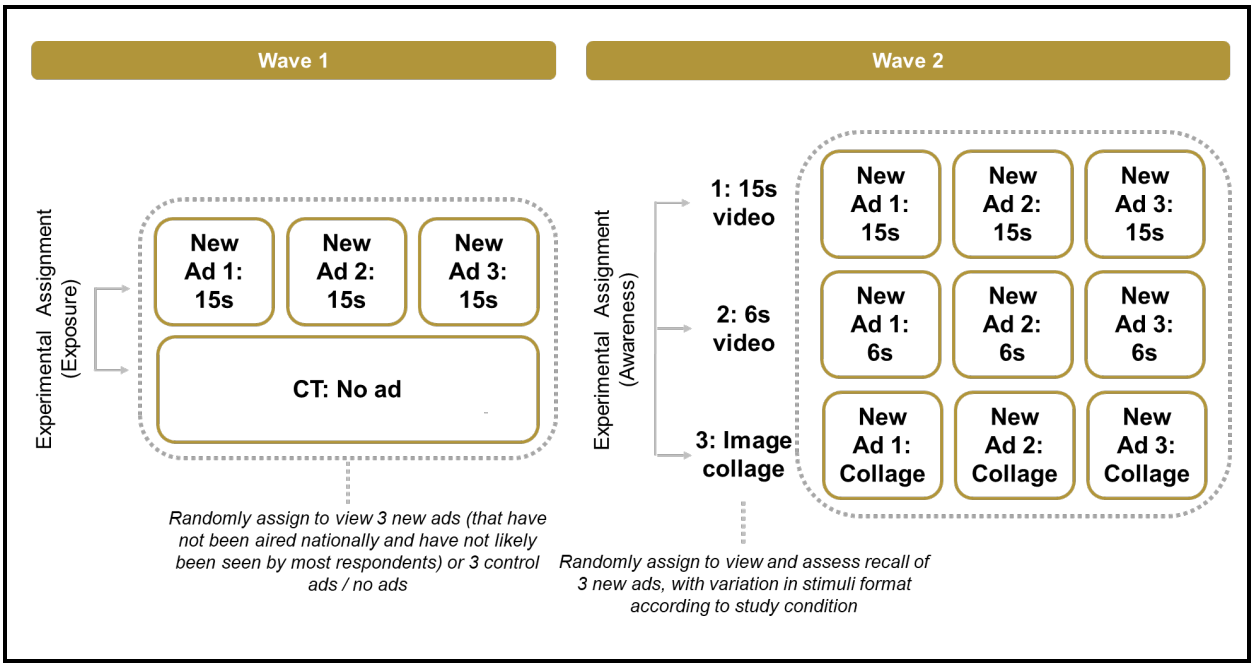
2) Wave 1 will also include a study (Study 1) to address RQs 1 (*To what extent does campaign awareness vary by measurement approach?)* and 3 (*Which awareness measurement approach is most sensitive to variation in campaign exposure?)* under Objective 1. Study 1 will use a 3x3 factorial design with factors of recall period (3 levels: 1 week, 1 month, and 3 months) and stimuli format (3 levels: 6-second video, 15-second video, and image collage). Respondents will be randomly assigned to one of 9 conditions using adaptive randomization to ensure balanced distribution across conditions. Following assignment to condition, respondents will be shown 3 Real Cost ads, with variation in stimuli format according to study condition, and asked to indicate frequency of having seen the ad, with variation in recall period according to study condition. Ad awareness will be assessed separately for each of 3 ads. Figure 1 illustrates the study design for Study 1.

Figure 1. Study 1 design



3) We will conduct a second study (Study 2) to assess RQ2 (*Which awareness measurement approach is most valid?)* under Objective 1. This study will use a 2x3 factorial design with factors of ad exposure (two levels: exposed and unexposed) and stimuli format (3 levels: 6-second video, 15-second video, and image collage). At the conclusion of the Wave 1 survey, we will randomly assign participants to either an exposure condition, in which they will be shown 3 new 15-second Real Costs ads that have never aired or have not aired recently (in randomized order), or a control condition with no ad exposure. Next, participants who completed Wave 1 will be recontacted approximately 1-2 weeks later to invite their participation in a second survey. In the Wave 2 survey, participants will be randomly assigned to a stimuli format condition (6-second video, 15-second video, and image collage). Following assignment to condition, respondents will be shown the 3 Real Cost ads that were shown in Wave 1 survey, with variation in stimuli format according to study condition. Ad awareness will be assessed separately for each of 3 ads. Figure 2 illustrates the study design for Study 2.

Figure 2. Study 2 design



Recruitment and survey administration

Participants will be recruited by an online survey vendor, Lightspeed, that manages a national online panel of adults. Lightspeed may partner with other survey vendors who maintain online panels. These partner vendors will only participate in recruitment and administering incentives to their own panel members; they will not be involved in survey programming, survey hosting, data collection, or data storage. All aspects of data collection (screener, consent, and survey administration) will be hosted by Lightspeed, regardless of the panel through which the participant was recruited.

Lightspeed will identify adults from this database who are likely to have eligible children based on the number of children in the home and their ages. Lightspeed will send an initial generic communication to parents through the panelist portal indicating that they have a new survey available. If a parent clicks on this communication, they are directed to the parental permission form. If a parent provides permission, we will ask for the child's assent to participate and screen them to determine eligibility. Participants will be screened based on age (13-17). Those who meet the eligibility criteria will continue with the study and otherwise will be excluded from the study. In appreciation of their child's participation in the surveys, adult panelists will receive non-monetary points that can be redeemed for goods, services, or cash.

2b. Degree of Accuracy Required for the Study

For the purposes of estimating statistical power, we assumed a Study 1 sample size of 2,400 participants with equal allocation (n = 267) to each of nine groups. For Study 2, we conservatively assumed a 50% retention rate, yielding an estimated sample size of 1,200 with

equal allocation (n = 200) to each of 6 groups. For Study 1, we estimate being 80% powered to detect a main effect size of 0.14 (i.e., a difference of 0.14 in mean awareness scores between two levels of a study factor). For Study 2, we estimate being 80% powered to detect a 9.8% difference in proportions recalling an ad between stimuli format groups (assuming 50% ad recall for the comparison group).

2c. Estimation Procedures

Statistical analyses will be conducted to address the study's primary research questions.

For Objective 1 (*Examine the extent to which the distribution and accuracy of self-reported awareness varies across different awareness assessment approaches*), we will conduct descriptive analyses and develop multivariable models to examine statistical associations between study condition and self-reported ad awareness and recall.

For Objective 2 (*Develop comprehensive, valid, multi-item scales to measure outcomes such as addiction perceptions, expectations of feeling anxious after using tobacco, and other key predictors of tobacco use that campaign messages aim to change*), we will examine the factor structure of outcome items and assess scale reliability and validity according to best practices in scale development.[1]

3. Methods to Maximize Response Rates and Deal with Nonresponse

To maximize participation, we will incorporate best practices from similar online surveys into our data collection procedures. These include:

- Implementing a soft launch of the online survey to a small number of selected panel members to detect and resolve any technical difficulty.
- Keeping the questionnaire at a reasonable length to minimize break-offs.
- Including a brief introduction to the study that identifies FDA as the sponsor, states the purpose of the study, and provides toll-free telephones numbers for participants to call RTI with any questions about the study or their rights as a study participant.
- Inviting panel members who appear to be eligible based on their member profile. As part of the process of registering with the survey panel, panelists provide information about a range of sociodemographic characteristics, including whether or not they have children, that can be used to target particular groups. Lightspeed actively manages panelist profiles, requesting updated information on an ongoing basis to ensure that profile information is up to date.
- Recruiting verified panelists. Lightspeed uses a double opt-in registration process whereby panelists are invited to participate and then must sign up through an opt-in confirmation e-mail. This process protects against fraudulent account registrations and ensures that panelists are actively motivated to participate in surveys.
- To minimize nonresponse, Lightspeed will conduct ongoing monitoring of response levels and drop-off rates. Lightspeed will work with RTI project staff to address any problems that arise throughout the course of the collection of information.

[1] Boateng, G. O., Neilands, T. B., Frongillo, E. A., Melgar-Quiñonez, H. R., & Young, S. L. (2018). Best practices for developing and validating scales for health, social, and behavioral research: a primer. Frontiers in Public Health, 6, 149.

4. Test of Procedures or Methods to be Undertaken

RTI International will conduct rigorous internal testing of the online survey instruments prior to fielding. Survey testers will review the online test version of the instrument that we will use to verify that instrument skip patterns are functioning properly, and that all survey questions are worded correctly and are in accordance with the instrument approved by IRB and OMB. Lightspeed will begin data collection with a soft launch during which they will send a generic communication to a small subset of panel members and review their responses to ensure the online survey is working properly.

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

The following individuals inside the agency have been consulted on the design and statistical aspects of this information collection as well as plans for data analysis:

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The following individuals outside of the agency have been consulted on questionnaire development and/or will be collecting and/or analyzing data:

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