Waterpipe Marketing Aim 3

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Protocol

Evaluating the Impact of Waterpipe Tobacco Marketing Claims on Young Adults
Aim 3 Survey

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Background, Rationale, and Context

Waterpipe tobacco (WT) smoking in the U.S. is common among young adults, with approximately 5.5 million current users. WT smoking is associated with many of the same health risks as cigarette smoking, but consumers often erroneously believe WT smoking is less harmful and less addictive than cigarette smoking. Package design is an effective tool used by the tobacco industry to communicate product information to consumers, including information related to health risks. The Food and Drug Administration (FDA) has begun to prohibit certain claims on WT packaging. Under Section 911 of the Family Smoking Prevention and Tobacco Control Act, manufacturers and retailers are prohibited from making unauthorized modified risk tobacco product (MRTP) claims, including statements that the product or its smoke: (1) results in reduced harm; (2) contains a reduced level of a substance or presents a reduced exposure to a substance; (3) does not contain or is free of a substance; and (4) statements that use modified risk descriptors such as *light*, *mild*, *low*, or *similar descriptors*. In addition, manufacturers and retailers are also prohibited from making false and misleading claims on packaging and in advertising under Section 903. Some prohibited claims are easily identifiable, but others are more difficult to identify due to lack of specificity in the law and the implicit nature of some claims. Evidence is needed specific to WT packaging and marketing to determine which claims may be associated with consumer harm misperceptions to inform future regulatory actions. The proposed study will address this gap by documenting WT packaging digital marketing (websites and social media) claims and how such claims influence consumer perceptions and behavioral intentions. In **Aim 1,** we will identify WT product packaging and digital marketing through a comprehensive website review to identify manufacturers (who make

tobacco for waterpipes) and retailers (who sell WT for onsite use such as cafés and lounges). We will create a sample frame of WT brands and flavors and will randomly select five flavors from 30 brand for purchase. For digital marketing, we will use the same 30 brands of WT and a random sample of 30 US-based retailers with websites and social media accounts. We will capture all website content and 20 of the most recent posts from Facebook and Instagram, the two most popular social media platforms among young adults. In **Aim 2**, we will content analyze all of the packaging and digital marketing content captured in Aim 1. We will them use an expert panel to determine whether claims found on the packaging and in the digital marketing are examples of unauthorized claims. In **Aim 3**, we will conduct an online experiment with a nationally-representative sample of young adults to evaluate the impact of unauthorized claims present on WT packaging and digital media on young adults' willingness to try the product, perceptions of harm, and product appeal. The findings will help the FDA determine which claims consumers interpret in ways that the law prohibits; which could prompt the FDA to engage in additional rulemaking so consumers are not misled.

Objective(s)

The overarching goal of this project is to evaluate the impact of unauthorized claims present on WT packaging and digital media on young adults' willingness to try WT, perception of harm, and WT product appeal.

Methods and Measures

Design

We will conduct an online experiment with a national probability-based sample (*n*=1,515) of young adults (ages 18-29) recruited from the AmeriSpeak panel, funded and operated by NORC at the University of Chicago, and a third-party non-probability panel. All panel members aged 18-29 will be invited to be screened, and those who have used in the past year (current users), as well as those who have not but are susceptible to use (susceptible) will be invited to participate. We will measure WT susceptibility with a four-item scale, validated by our team. We anticipate 9% of young adults ages 18-29 will be current WT users and 40% will be susceptible non-users. Given the young adult sampling frame available and estimated response rate from NORC, we anticipate recruiting 303 current waterpipe users and 1212 susceptible non-users. AmeriSpeak participants will receive points, worth approximately $5, for completing the survey. Third-party participants will receive compensation as agreed upon with their panel.

To assess eligibility, participants will be asked their age and several questions about waterpipe use and susceptibility. Then, participants will complete three distinct tasks. For the Packaging Task, participants be exposed to six different WT packages. For each package, participants will be randomly assigned to view a WT package with a prohibited or potentially-prohibited claim or a WT package without a potentially-prohibited claim. For the Digital Marketing Task, participants will view 10 digital marketing images (e.g., website or Instagram post). For each digital marketing images, participants will be randomly assigned to view the image with a prohibited or potentially-prohibited claim or without a potentially-prohibited claim. For the Claim Perception Task, participants will view up to four of the sixteen claims as a standalone (not on either the packaging or digital marketing). For all tasks, participants will complete questions while the stimuli are shown on the survey webpage. We will counterbalance the order of the Packaging and Digital Marketing Tasks. At the end of the study, participants will receive a link to electronic resources from the CDC about the harms associated with WT smoking.

Experimental Stimuli. All packaging, social media posts, and website claims will be manipulated in Photoshop to appear on fictitious brand packaging or digital marketing that mimic current designs. We will create a fictitious manufacturer (brand) and retailer for three reasons: (1) it allows for manipulation of claims on package and digital marketing while keeping all other design content constant; (2) it avoids using brand or retailer names which could influence responses due to existing brand/retailer perceptions or loyalty; and (3) it removes the potential for claims and brand/retailer to be completely confounded, as would be in most cases; therefore, creating a new brand/retailer removes this confounder.

Setting

Participants will complete the online survey at a computer in a location of their choosing.

Subjects Selection Criteria

We will conduct an online national probability-based survey with a sample of up to 1,515 U.S. young adults (18-29 years old) using the AmeriSpeak panel at NORC and a third-party non-probability sample, weighted with the AmeriSpeak sample to be nationally representative.

Screener

All interested individuals will be able to complete our screener. Interested individuals will click on the link to the survey and be routed to a website to review consent language and complete the screener. Participants will be consented and then complete a one-minute to determine if they are eligible for the full survey based on their age, waterpipe use, and susceptibility to waterpipe use.

Inclusion Criteria

- Adults ages 18+
- U.S. residents

Exclusion Criteria

- Non-U.S. residents

Full Survey

Eligible participants will be automatically invited to continue on to complete the full survey. Eligible participants are U.S. residents between the ages of 18-29 years old who fit into one of the two categories numbered below.

Inclusion Criteria

- Adults ages 18-29
- U.S. residents
- Satisfies one of the following categories:
    1) Has used waterpipe tobacco within the past year (estimated 303 participants)
    2) Has not used waterpipe tobacco within the past year but is susceptible to using waterpipe tobacco in the future (estimated 1212 participants)

Exclusion Criteria

- Persons below age 18 or above age 29
- Non-U.S. residents

Sample Size

- We estimate up to 1,515 of those screened will complete the full survey

Interventions and Interactions

Interested individuals will click on the link to the survey and be routed to a website to review consent language and complete the screener. Participants will complete a one-minute screener to determine if they are eligible based on their age and waterpipe tobacco use & susceptibility. After completing the screener, participants who are not eligible will be thanked for their time but will not receive an incentive. Those who are eligible will automatically be invited to continue on to the full survey. The full survey will last approximately 20-25 minutes. After completing the survey, participants will receive a small incentive in the form they've agreed to with their panel.

Outcome Measure(s)

PRIMARY

Willingness to try hookah tobacco. The Packaging Task) will use one item to assess the extent to which young adults are likely to try the waterpipe tobacco product: "**How likely would you be to try this specific product?"** Response scale (1) Not at all likely to (4) Very likely.

Willingness to smoke hookah
The Digital Marketing Task will use one item to assess the extent to which the advertisement makes young adults want to smoke hookah: "How much does this advertisement make you want to smoke hookah?" Response scale (1) Not at all to (4) A lot.

SECONDARY
None

OTHER
Absolute safety perception. The Packaging Task will use one item to assess young adults' perceptions of how the packaging influences their opinion of how safe the product is: "**How much does this packaging make you think this product is safe?"** Response scale (1) Not at all to (4) A lot. The Digital Marketing Task will use a similar item to assess the advertisement's impact on perception of the safety of smoking hookah: **"How much does this advertisement make you think smoking hookah is safe?"** Response scale (1) Not at all to (4) Very. For the first stimulus shown only, participants will be asked to provide the words or elements that led them to their perception; this item is descriptive.

Relative safety perception. The Packaging Task will use one item to assess young adults' perceptions of how safe the product pictured is as compared to other products that may be available to them: **"Compared to other hookah tobacco on the market, how safe do you think this specific product is?"** Response scale (1) Much less safe to (5) Much more safe.

Absolute harm perception. The Packaging Task will use one item to assess young adults' perceptions of how the packaging influences their opinion of how harmful the hookah tobacco pictured is: **"How much does this packaging make you think this product is harmful?"** Response scale (1) Not at all to (4) A lot. The Digital Marketing Task will also use one item to assess young adults' perceptions of how harmful hookah smoking is, based on the advertisement pictured: **"How much does this advertisement make you think smoking hookah is harmful?"** Response scale (1) Not at all to (4) A lot. For the first stimulus shown only, participants will be asked to provide the words or elements that led them to their perception; this item is descriptive.

Product appeal. The Packaging Task will use one item to assess young adults' opinions of the appeal of the product shown: **"How appealing is this specific product to you?"** Response scale (1) Not at all appealing to (4) Very appealing. The Digital Marketing Task will use one item to assess their opinions of the appeal of smoking hookah, in context of the advertisement: **"How appealing does this advertisement make smoking hookah seem to you?"** Response scale (1) Not at all appealing to (4) Very appealing.

Analytical Plan

For the primary outcomes, linear regression analyses will examine differences in the mean outcomes between the two randomized conditions. This analysis will be performed for each of the 6 packages and 10 digital marketing images. Models will adjust for age, sex, race, ethnicity, waterpipe use status (current user, susceptible non-user), and use of other tobacco products The order in which the two tasks were performed will be included as a covariate, but if no significant order effects are detected, this covariate will be removed from the model. After testing for main effects, we will explore interactions with user status and sex. The same set of models will be fit for the secondary and other outcomes. Statistical significance will be set at $p<0.05$ for all analyses.

Human Subjects Protection

Subject Recruitment Methods

We will recruit participants using the AmeriSpeak panel at NORC. All panel members ages 18-29 will be invited to complete the screener to determine eligibility. Eligible participants will continue to review the informed consent and complete the full survey. NORC will also work with a third party non-probability sample to recruit participants to achieve accrual goals, if not met through AmeriSpeak.

Informed Consent

Since the study is exempt, consent is not required. However, before the survey, participants will be provided with a study information sheet to describe the study and participants will be asked to check a box to indicate that they agree to participate.

Confidentiality and Privacy

Confidentiality will be protected by collecting only information needed to assess study outcomes, minimizing to the fullest extent possible the collection of any information that could directly identify subjects, and maintaining all study information in a secure manner. Data will be collected and housed on the secure NORC server, and de-identified data will be provided to the Wake Forest team.

Access to de-identified data will be limited to study staff. Data and records will be kept locked and secured, with any computer data password protected. No reference to any individual participant will appear in reports, presentations, or publications that may arise from the study.

Data and Safety Monitoring

The Principal Investigator, Dr. Sutfin will be responsible for the overall monitoring of the data and safety of study participants. Dr. Sutfin will be assisted by other members of the study staff. It will also be monitored closely by the Wake Forest School of Medicine IRB.

Reporting of Unanticipated Problems, Adverse Events or Deviations

Any unanticipated problems, serious and unexpected adverse events, deviations or protocol changes will be promptly reported by the principal investigator or designated member of the research team to the IRB and sponsor or appropriate government agency if appropriate.