Cigarillo Warning Labels: Experimental Tobacco Marketplace Protocol

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Background, Rationale, and Context

In the U.S., cigar smoking (including cigarillos) remains a significant public health concern. From 2000 to 2015, consumption of cigars increased 85%, while cigarette consumption decreased 39%.[1] Cigarillo use has increased further during the COVID19 pandemic.[2] Over 70% of cigar users aged 18-29 report cigarillos as their typical cigar type and 39.4% of young adults have ever used cigarillos.[3,4] Cigarillo use is particularly high among vulnerable populations, including young adults and Black or African American people.[4–6] Cigarillo smoke contains toxic chemicals,[7–12] and smoking causes significant health consequences, including nicotine addiction, cancer, heart disease, and lung disease.[13] Negative health effects of consistent cigar use (including cigarillos) result in 9,000 premature deaths and 140,000 years of potential life lost annually, accounting for $23 billion in lost economic value.[14] However, some young adults erroneously believe that cigarillos are less harmful and less addictive than cigarettes.[15,16] These misperceptions contribute to cigarillo use.[17–19]

One approach for conveying the health risks of cigarillo smoking and discouraging use is through warning labels. The Food and Drug Administration (FDA) has regulatory authority over cigarillos and requires the display of six rotating <u>text-only</u> warnings on cigarillo packaging. These warnings have not been implemented due to litigation. Pack warnings are effective because consumers are exposed to them at multiple points: at the point-of-purchase and prior to each use.[20,21] We posit that cigarillo warnings could be strengthened by adding images depicting the health consequences of smoking. Data consistently show that pictorial warnings (text warnings that also include an image) for cigarettes are more effective than text-only warnings on several outcomes, including attention to the warning, intent to quit, intent to not

initiate, cessation, reducing smoking urges, forgoing cigarettes, and reducing cigarette purchasing behaviors.[22–26] However, little is known about the impact of cigarillo warnings on behavior.[27]

In our previous work (R03CA206487, PI Ross) we developed pictorial cigarillo warnings by pairing images with the six FDA text-only cigar warning statements. In an online study with a nationally representative sample, we found that pictorial warnings were more effective at eliciting negative emotional reactions than text-only warnings among young adult cigarillo users and susceptible nonusers. They were also perceived as more effective at discouraging future cigarillo use. We now seek to understand the impact of cigarillo warnings on behavior and intentions at the point-of purchase and after repeated exposure. The presence of warnings that communicate about risk can result in negative emotional reactions and cognitions about the harms of smoking, which may deter purchase. Warnings are also effective after multiple exposures over time through message repetition.[28]

A behavioral economics framework can model the impact of implementing a cigarillo warnings policy on consumer purchasing behavior in the context of a complex tobacco product marketplace. Behavioral economics frames potential policy measures as ways to decrease the value of a tobacco product for an individual.[29,30] In this framework, warning labels may work to reduce the value of a product. Value is often measured as demand, or consumption of a product at increasing prices. In behavioral economics, changes in price are considered to be analogous to *changes in effort required* to obtain the product, which indicates value for that individual. There has been a recent call to use a behavioral economics framework for communications research in tobacco regulatory science and apply it to products other than cigarettes.[31] The Experimental Tobacco Marketplace (ETM) task examines the effects of regulations on tobacco purchasing in the context of a complex tobacco marketplace.[52] Instead of 'switching' from one product to another, participants can choose a mix of tobacco products from an online store. In a typical ETM, across multiple task (i.e., shopping trips) trials, the price of the preferred tobacco product (cigarillos in this study) increases and those of other tobacco products remain constant.[53,54] Increasing price across shopping trips measures effort required to obtain the product (product demand), and substitution with other products.

The proposed study will contribute to the evidence base needed to support the rulemaking process and will have a significant public health impact. The FDA's CTP has an interest in effectively communicating the risks of tobacco products, including cigarillos. However, there is a critical gap in the science on how to inform the public of the risks of cigarillo use. This project aims to address the gap in the knowledge about cigarillo risk communication by providing information on best practices for cigarillo warnings. Identifying effective cigarillo warnings is important to inform policy and guide research on effectively communicating risk to ultimately decrease use and tobacco-related morbidity and mortality.

Objective(s)
This Experimental Tobacco Marketplace online survey experiment aims to determine the impact of cigarillo warning format on hypothetical purchasing behaviors.

Methods and Measures
Design

We will conduct a three-group, between-subjects experiment to compare varying cigarillo warning formats: Surgeon General text-only, FDA-proposed text-only, and our developed pictorial cigarillo warning labels. This will be a single survey study.

Setting
Survey participants will complete the online survey in a location of their choosing.

Subjects Selection Criteria
Participants will be recruited by Kantar, a leading data and consulting company with access to 21 million respondents in the United States. Kantar has participated in survey programming and data collection for various social science and public health studies, including tobacco. They will recruit a total of 1,575 cigarillo users, including oversampling Black/African American cigarillo users, with an estimated total of 635 Black/African American and 647 White cigarillo users

Inclusion Criteria
- Age 21-35
- Current cigarillo users: used cigarillos at least one time per week in the past month
- Members of the Kantar Media panel

Exclusion Criteria
- Non-English speakers
- Non-current cigarillo users
- Not members of Kantar Media

Sample Size
- We estimate 1575 participants will be eligible to complete the survey.

Interventions and Interactions
Kantar will contact individuals to participate, who will complete an eligibility screener. Eligible participants will first complete measures of demographics and tobacco use behaviors. Next, participants will be <u>randomized</u> to one of three experimental conditions to complete six purchasing tasks (i.e., mock shopping trips). Participants will indicate their preferred brand and flavor of cigarillos.[32] If their preferred brand of cigarillo is not one of the top four brands, we will ask them to select one of the available brands. The experimental stimuli will be placed on that branded packaging.

We will ask participants the average amount of money they spend each week on tobacco products; they will receive that balance for each mock (i.e., hypothetical) shopping trip, as is standard for ETM studies.[33] We will ask participants to imagine they were shopping in a convenience store, and to view six items available for purchase: preferred cigarillo brand, cigarette product (menthol and non-menthol), e-cigarette product (three variations), oral nicotine pouches, non-alcoholic drink, and snack food. They will be instructed to make hypothetical purchases of tobacco products that they would use for the week. In each shopping trip, the price of cigarillos will increase while those of alternative products remain the same. In each trial, participants can choose any combination of tobacco and non-tobacco products to 'buy', as long as they stay within their experimental budget. Across six mock shopping trips, the price of one of their preferred cigarillo products will increase from $0.25, 0.50, $0.75, $1.50, $3.00, $6.00, based on an average price of $0.91 per cigarillo.[34] Cigarette price will remain constant at $6.00 per pack ($0.30 per cigarette), e-cigarettes will be priced at $4 per e-liquid pod or $6 for 30 ml e-

liquid or $12 for disposable device, and oral nicotine will be priced at $4.00. Food and drink will be priced at $2 each. Cigarillos will be purchased as singles to generate demand curves (see Measures and Analysis Plan).. This models other ETM studies.[33]

After completing the hypothetical purchase tasks, we will assess additional constructs from our conceptual model. First, we will assess cigarillo warning label recognition (a measure of attention). We will then show the cigarillo warning to participants from their assigned experimental condition and ask them to respond to items assessing negative affect, thinking about the warnings, and intentions to quit using cigarillos.

At the end of this experiment, participants will view a **debriefing** page, including an explanation of the purpose of the study, emphasizing that the study is not promoting the use of cigarillos or any tobacco product and will include links to cessation services and information about the harms of cigarillo use. Participants will be compensated with 100 points (~$2 value) by Kantar. These points can be used in exchange for a variety of items, including gift cards. We will not collect any identifying information such as name or birthdate.

Outcome Measure
The average total number of cigarillos purchased is the primary outcome.

We will assess secondary outcomes: average total amount (mg) of combusted and non-combusted tobacco purchased in the ETM.

In secondary analyses, we will also generate demand indices for cigarillos, including: demand intensity (consumption at the lowest cigarillo cost), demand elasticity (rate of change in demand for cigarillos), price of cigarillos resulting in maximum purchasing, the amount of money spent at the maximum purchasing price.

In exploratory analyses, we will assess cross-price elasticity measures, negative affect, cognitive elaboration (thinking about the warnings), intentions to quit using cigarillos, perceived message effectiveness, and warning recall/recognition, which is a measure of attention.

We will also measure several *covariates*: use of other tobacco products, cigarillo dependence, sexual orientation, race/ethnicity, socioeconomic status, sex, gender identity, and age.

Analytic Plan
This study will examine the impact of cigarillo warnings on purchasing behavior in a hypothetical shopping task using the online Experimental Tobacco Marketplace. The primary outcome is the average total amount of cigarillos "purchased" (hypothetical shopping task) compared across study conditions.

Baseline differences between participants (e.g., sex) across warning conditions will be examined using t-tests for continuous variables and χ^2 tests for categorical variables to evaluate randomization balance. The primary outcome, average total number of cigarillos purchased, will be modeled using random-effects linear regression models to account for the within-person correlation among the repeated measures represented by the six purchasing tasks. Warning condition will be included as a between-subjects fixed effect. Models will control for any variables that differ at baseline between conditions. We will also assess whether Black/African-American race moderates the effect of warning condition by including interaction terms between Black/African American race and warning condition. These same analyses will also be

conducted for our secondary outcomes for average total of mg combusted and non-combusted tobacco products.

In secondary analyses, demand curves will be generated for each cigarillo warning condition in each of the ETM conditions using the exponential demand equation, $Q = Q_0 * 10^{k(e^{-\alpha Q_0 C} - 1)}$, where Q is the mg of nicotine purchased at a given price, Q_0 is peak demand consumption or intensity (typically occurring at the lowest price), k is a constant across all compared conditions, and alpha (α) is the rate of change in demand or elasticity.[35] To determine the extent to which pictorial warnings decrease cigarillo purchasing relative to the text-only warning conditions, the global fits of the demand curves for cigarillos from each condition will be compared using an extra-sum-of-squares F-test, which compares whether the fitted parameters (specifically, Q_0 and α) are significantly different across each curve. A significant difference in α would represent a difference in the essential value of the product, while a difference in Q_0 would indicate that purchasing was reduced in absolute terms but the underlying 'value' of the product was unchanged.[36,37] Finally, each individual demand index will be compared across conditions using t-tests to determine if pictorial warnings affected specific indices of demand differentially. The number of cigarillos purchased is higher for text-only warnings compared to pictorial warnings at the same price, but demand overall will decrease as price increases.

Exploratory analyses will examine the effects of warning condition on other constructs in the conceptual model including negative affect, cognitive elaboration, behavioral intentions, and warning recall/recognition . Because these outcomes are measured only once after the completion of all six purchasing tasks, continuous outcomes will be modeled using standard linear regression modeling and categorical outcomes will be modeled using logistic and multinomial regression. All tests will be two-sided with a 0.05 significance level.

In exploratory analyses, to determine the extent to which each alternative product substituted for cigarillos, cross-price elasticities will be calculated as the slope of the regression line (B_1) fit to the log-transformed mean purchasing in mg of nicotine for each alternative tobacco product when offered at fixed prices (C) versus log-transformed cigarillo price (P): $logC = B_0 + B_1 logP$. Positive values indicate product substitution. We will use PRISM GraphPad Version 8.1.1 to generate the behavioral economics indices, demand curves, and cross-price elasticities. We will be able to determine if viewing a pictorial warning on a cigarillo resulted in substitution with another tobacco product without a pictorial warning, such as cigarettes or e-cigarettes, or a non-tobacco product, such as food or drink.

Every effort will be made to minimize the presence of missing data. Analyses will use all available data. Since missing data in a single item of a multi-item scale leads to a missing total, we will consider imputing both at the level of the item and scale total. Additionally, to evaluate the generalizability of our results, we will use *t*-tests and chi-squared tests to examine pairwise differences in characteristics between participants for whom we have complete data and those for whom we do not.

Human Subjects Protection
Subject Recruitment Methods
Kantar works with permission-based panels with 88 million respondents, including 21 million in the United States. Recruitment includes traditional advertising and through internal and external affiliate networks. Kantar uses a diverse set of sources to reduce panel bias. When recruiting participants into studies, Kantar engages in data validation to ensure quality respondents and

responses. Kantar will recruit participants, directly inviting them to participate in the experiment. Potential study participants will complete an eligibility screener for inclusion into the ETM study. Participants must be ages 21-34 and be current cigarillo users (use cigarillos at least one time per week for the past month). Further, because we are studying cigarillo warnings in the U.S., only those living in the U.S. are eligible. Kantar will also oversample for young adult Black/African American cigarillo users. Kantar oversamples by enrolling approximately 20% additional participants to the study.

Informed Consent
Participants will read an electronic version of the informed consent form, and will be asked to select a checkbox to confirm their consent. The consent form will explain the study's purpose, potential risks, expected benefits, protection of confidentiality, and time expectations. Contact information for the local IRB and PI (Dr. Ross) will be provided in case the participant has concerns or questions about the study.

A waiver of signed consent/assent is requested. This is an online survey and individual participation involves providing voluntary responses to survey questionnaires. The research presents no more than minimal risk of harm to subjects. Consent language will be included in the introduction to the survey and participants will be asked to click a button to confirm their consent/assent:

ELECTRONIC CONSENT: Please select your choice below.

Selecting "Yes" below and clicking "Next" indicates that:
• you have read the above information
• you voluntarily agree to participate
• you are at least 18 years of age

Do you wish to participate in this research study?
☐ Yes
☐ No

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. We will receive only de-identified data from Kantar.

Kantar maintains appropriate technical, administrative and physical safeguards to protect PII and other information disclosed or collected by Kantar. Kantar reviews, monitors and evaluates its privacy practices and protection systems on a regular basis.

All personally identifiable information (PII) is stored on servers located in the United States, which are owned and maintained by Kantar. Kantar will provide survey data and responses to Kantar clients with no PII disclosed by Kantar.

Once we receive de-identified data from Kantar, data access will be limited to study members. 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. Ross will be responsible for the overall monitoring of the data and safety of study participants. Dr. Ross 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 Dr. Ross to the IRB and sponsor or appropriate government agency if appropriate.

Appendix
1. **Study survey**
2. **Cigarillo warning stimuli**

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