Centering equity in FDA regulation: Front-of-package food label effects in Latiné and limited English proficiency populations

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Study Protocol and Analytic Plan

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Introduction

This study aims to determine the front-of-package label design that is most effective at helping Latiné consumers identify healthier products and to explore whether the benefits of front-of-package label design differ by English proficiency. This document pre-specifies our planned analytic approach prior to data collection.

Study Protocol

Participants will complete an online randomized experiment programmed in Qualtrics. After providing informed consent, participants will be randomly assigned to view 1 of 4 types of front-of-package nutrient labels: numerical label, interpretive text-only label, interpretive label containing a magnifying glass icon, or separated interpretive labels containing a magnifying glass icon. Participants will view 3 sets of similar products (with 3 products per set) displaying their assigned label type and will answer selection questions about the products. These selection questions will be repeated 3 times, once for each food product. The survey will also ask questions about reactions to the labels and demographics in the online survey.

Hypotheses

Correct identification of healthiest product (co-primary outcome): We predict that correct identification of the healthiest product will be highest for participants assigned to the separated interpretive magnifying glass icon label, followed by the interpretive magnifying glass icon label, the interpretive text-only label, and the numerical label (H1).

Correct identification of least healthy product (co-primary outcome): We predict that correct identification of the least healthy product will be highest for participants assigned to the separated interpretive magnifying glass icon label, followed by the interpretive magnifying glass icon label, the interpretive text-only label, and the numerical label (H2).

Correct identification of products high in nutrients (secondary outcome): We predict that correct identification of which products are high in nutrients of concern will be highest for participants assigned to the separated interpretive magnifying glass icon label, followed by the interpretive magnifying glass icon label, the interpretive text-only label, and the numerical label (H3).

Selection of healthiest product for purchase (secondary outcome): We predict selection of the healthiest product will be highest for participants assigned to the separated interpretive magnifying glass icon label, followed by the interpretive magnifying glass icon label, the interpretive text-only label, and the numerical label (H4).

Main Analyses

We will use a two-sided critical alpha of 0.05 to conduct all statistical tests. All confidence intervals presented will use a 95% confidence level. Analyses of the primary and secondary outcomes will include all participants according to the trial arm to which they were randomized.

For all of the selection tasks, participants will have a time limit to simulate real-world conditions where people make shopping decisions quickly. We will recode missing data as “no” or “incorrect” for all 4 selection outcomes. The healthiest product is defined as the one that is high in the fewest number of nutrients of concern (i.e., only 1 nutrient). The least healthy product is defined as the one that is high in the highest number of nutrients of concern (i.e., 3 nutrients). Correct identification of products high in nutrients is defined as identifying the products having 20% or more of the daily value of the nutrient or labeled with “high in,” per FDA’s guidance around “high” levels of nutrients of concern. The responses to these three correct identification tasks will be dichotomized as correct vs. incorrect. For the selection outcome, we will dichotomize the outcome to selection of the healthiest product vs. selection of either of the other two products.

We will descriptively report unadjusted means for the primary and secondary outcomes for each experimental arm. To test H1-H4, analyses will use mixed effects logistic regression models to examine the impact of label arm on the outcomes, accounting for repeated measures within participants. Models will regress the outcome on indicator variables for the labeling arm (excluding the numerical label as the referent) and indicator variables for product category, treating the intercept as random. Analyses will calculate average differential effects for each interpretative label compared to the numerical label, representing the differences in predicted probabilities by label type. We will also compare each interpretive label to each other. We will not adjust the p-value for each label type compared to the numerical label. We will adjust for multiple tests for the three additional pairwise comparisons (within each family of outcomes) among interpretive labels using a Bonferroni-Holm correction.

Exploratory Analyses

In exploratory analyses, we plan to report the impact of label type on the primary and secondary outcomes when stratifying by product type.

To examine whether the impacts of front-of-package label design on the co-primary outcomes differ by English proficiency, we will regress outcomes on label type, product type, English proficiency (high vs. limited), and the interaction between label type and English proficiency. These analyses will use linear probability models (rather than logistic regression) to aid in interpretation, as recommended for examining moderation for binary outcomes. We will use the same approach to determine whether the impacts of front-of-package label design differs by parental status.

Additionally, the survey will display 4 types of icon labels in random order, asking participants which label best signals when foods are high in sodium, saturated fat, and added sugars and which label most discourages purchasing of foods high in these nutrients. To assess which icon designs are most promising for front-of-package nutrition labels, we will calculate the proportion of participants who selected each label as best signaling when foods are high in sodium, saturated fat, and added sugars and the proportion who selected each label as most discouraging of purchasing foods high in these nutrients.

Sample Size and Power

We used G*Power 3 to estimate sample size needs. To be conservative, we powered the study to detect a difference in the co-primary outcomes between the 2 label designs that we anticipate will be most similar (i.e., the interpretative magnifying glass icon and interpretative text-only label). Power analyses assumed 55% of participants in the interpretative magnifying glass icon

condition would correctly identify the least healthy and healthiest products (based on a prior study using similar methods) and a two-tailed critical alpha of 0.017 (0.05 divided by 3 to correct for multiple comparisons). Under these assumptions, a sample of 1,000 per condition (4,000 total) yields 80% power to detect effects of OR=1.16 or larger between any 2 label designs for each primary outcome. This is a conservative estimate of effect size based on prior studies showing effect sizes of 1.10–1.80 between similar labels. This would be considered a small effect size, equivalent to Cohen's d=0.08.

Interim Analysis

No interim analyses are planned.

Exclusions and Outliers

We will exclude participants who complete the survey implausibly quickly (defined as <1/3 of the median completion time). We will exclude participants who complete less than 90% of the survey.