Complete Title: Online Randomized Experiment Evaluating Front-of-Package Nutrition Labeling Systems
Short Title: Front-of-Package Nutrition Labels
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Protocol Synopsis

Study Title	Online Randomized Experiment Evaluating Front-of-Package Nutrition Labeling Systems
Funder	NIDDK
Clinical Phase	NA
Study Rationale	• Poor diet quality accounts for approximately 500,000 deaths in the US every year. • One important barrier to improving diet quality is that consumers often lack access to easy-to-understand nutrition information. To address this barrier, experts and policymakers have called for the US to adopt a front-of-package labeling system that would help interpret product healthfulness for consumers. • A variety of front-of-package labeling systems have been proposed. It remains unclear which of these systems is most effective at improving the healthfulness of consumers' grocery selections and increasing consumer understanding of product healthfulness.
Study Objective(s)	The primary objective is to evaluate whether different front-of-package labeling systems improve the healthfulness of consumers' grocery selections.
Study Design	Randomized trial.
Subject Population key criteria for Inclusion and Exclusion:	Inclusion Criteria 1. Aged 18 years or older 2. Reside in the US 3. Can read and speak English 4. Are their household's primary shopper (do 50% or more of the grocery shopping for their household) Exclusion Criteria 1. Under the age of 18 2. Reside outside of the United States 3. Unable to complete a survey in English 4. Are not their household's primary shopper (do <50% of the grocery shopping for their household)
Number of Subjects	5,610
Study Duration	Each subject's participation will last approximately 20 minutes. The enrollment period is expected to last ~4-6 weeks.
Study Phases	There are two phases: (1) Screening: screening for eligibility and obtaining consent and (2) Intervention: study intervention/experimental treatment.

Efficacy Evaluations	The primary outcome is healthfulness of participants' grocery selections in a shopping task. It is measured as the weighted average Ofcom Nutrient Profiling Model score of the products the participants select in the shopping task. Secondary outcomes include selection outcomes (e.g., Guiding Stars scores of selections, calorie density of selections) and psychological outcomes (e.g., noticing of trial labels,
Statistical and Analytic Plan	We will use ordinary least squares regression to examine the effect of the front-of-package labeling systems on continuous outcomes (e.g., healthfulness, calorie density). We will use Poisson regression to examine the effect of the front-of-package labeling system on count outcomes (i.e., number of products selected that were high in 1 or more nutrient of concern). We will use logistic regression to examine the effect of the front-of-package labeling systems on binary outcomes (e.g., noticing of the front-of-package labels). Finally, we will use mixed effects logistic regression to examine the effect of the front-of-package labeling systems on consumer understanding.
Data and Safety Monitoring Plan	• The principal investigators are responsible for data quality management and ongoing assessment of safety.

Introduction

The goal of the analyses described here is to use data we collected through an online randomized experiment to examine consumer responses to different front-of-package food labeling systems. These analyses examine the effects of six front-of-package food labeling systems: 1) positive labels, 2) spectrum labels, 3) FDA high in labels, 4) FDA traffic light labels, 5) FDA high in labels plus positive labels, or 6) FDA traffic light labels plus positive labels.

This analysis plan pre-specifies the analyses before collecting data and therefore serves as our ex-ante planned analysis.

Study Protocol

Participants will complete an online randomized experiment. After providing informed consent, participants will be directed to complete a shopping task in a naturalistic online store. Participants will be instructed to shop as they usually would for items in the following categories: non-alcoholic beverages (e.g., juice, coffee, tea, soda, sports drinks, water), breads and baked goods, breakfast cereals, soups, boxed and frozen meals, and snacks (e.g., chips, crackers, nuts, applesauce, dried fruit). They will be given a budget based on average spending in these categories in a large supermarket chain. To complete the shopping task, participants will be required to spend between 0.5 and 1.5 times the budget, but otherwise will be free to select whichever products they choose. To incentivize truthful responding, participants will be instructed that 1 in 50 will be chosen at random to receive their selections delivered to their home and the remainder of their shopping budget as an electronic gift card.

After completing the shopping task, participants will respond to an online survey programmed in Qualtrics.

Statistical Considerations

General Principles

We will use a two-sided critical alpha of 0.05 to conduct all statistical tests. All confidence intervals presented will be 95% and two-sided. Because we expect minimal missing data based on prior similar studies,[1–3] we will use complete case analysis to handle any missing data in analyses of the primary and secondary outcomes.

Primary Outcome

The primary outcome is healthfulness of participants' selections, operationalized as the weighted average Ofcom Nutrient Profiling Model score of the products the participants select in a shopping task, weighted by the number of servings in each product.

Secondary Outcomes

The secondary outcomes are:

- Selection outcomes:
    1. Guiding Stars score
    2. Number of items selected that are high in ≥1 nutrient of concern
    3. Calorie density, kcal per 100g
    4. Sugar density, g per 100g
    5. Sodium density, mg per 100g
    6. Saturated fat density, g per 100g
    7. Fiber density, g per 100g
    8. Protein density, g per 100g
    9. Total calories selected, kcal
    10. Total sugar selected, g
    11. Total sodium selected, mg
    12. Total saturated fat selected, g
    13. Total fiber selected, g
    14. Total protein selected, g
    15. Total items selected
    16. Spending, USD ($)
- Psychological outcomes
    17. Consumer understanding, % correctly identifying healthier item
    18. Noticing, % who noticed the labels
    19. Use of labels, % who used the labels when shopping
    20. Thinking about health
    21. Negative emotional reactions
    22. Perceived helpfulness
    23. Perceived understandability
    24. Perceived trustworthiness
    25. Public support for requiring this labeling system

Statistical Methods

1. We will describe participant characteristics by trial arm. We will use means and standard deviations to characterize continuous variables (such as age), and frequencies and percentages to characterize categorical variables (such as gender and educational attainment).
2. Analyses of the primary outcome:
    a. We will use ordinary least squares regression to evaluate the effects of the front-of-package labeling systems on healthfulness of participants' selections. We will regress healthfulness on indicator variables for each of the front-of-package labeling systems, excluding the positive labeling system as the referent category. We will use the models to estimate average differential effects (ADEs, i.e., differences in predicted means between groups) for each labeling system compared to the positive labeling system.
    b. We will test whether the effects of the 5 labeling systems (other than the positive labeling system) on healthfulness of participants' selections differ from one another using Wald tests.
    c. We will test whether the effects of the labeling systems on healthfulness of participants' selections are moderated by nutrition literacy (assessed with an adapted version of the Newest Vital Sign measure of health literacy[4]), annual household income, and educational attainment. To test for moderation, we will regress healthfulness on the moderator, indicators for each of the front-of-package labeling systems, and the interaction between the labeling systems and the moderator, using separate models for each moderator. We will test the joint significance of the interaction terms and report effects of the labeling systems at different levels of the moderator.
3. Analyses of secondary outcomes:
    a. We will use ordinary least squares regression to evaluate the effects of the front-of-package labeling systems on continuous secondary outcomes (e.g., Guiding Stars score, calorie density); logistic regression to evaluate effects on binary outcomes (e.g., noticing); Poisson regression to evaluate effects on count outcomes (e.g., number of items selected that are high in ≥1 nutrient of concern); and mixed effects logistic regression to evaluate effects on repeated measures binary outcomes (i.e., consumer understanding of product healthfulness). We will regress the outcome on indicator variables for each of the front-of-package labeling systems, excluding the positive labeling system as the referent category. We will use the models to estimate ADEs for each labeling system compared to the positive labeling system.

Sample Size Needs

We plan to collect data from 5,610 participants. We used G*Power to estimate sample size needs.[5] We estimated sample size needs to detect an effect of each labeling system vs. the positive labeling system. Assuming an alpha=0.05, a sample of 5,610 will yield 90% power to detect a standardized effect of Cohen's *d*=.15 or larger and 80% power to detect a standardized

effect of *d*=.13 or larger of each labeling system vs. the positive labeling system. These effects would be considered small.[6] Prior studies comparing different front-of-package labeling systems to positive front-of-package labeling found similar effect sizes.[1,3,7]

Exclusions and Outliers

We will exclude participants who do not complete the shopping task (for whom we will not have data on the primary outcome) or who complete the survey implausibly quickly (defined as completing in less than one-third of the median completion time).

References

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