

Attachment 20

PATH Study
Sample Analysis Plans

June 26, 2014

Sample Data Analysis Plan For Packaging And Health Warning Labels Domain

Key outcomes: Uptake; Quitting; Relapse

Key variables: Health warning labels; Light/mild/low tar; Menthol; Other Flavors; Other packaging and labeling changes

Covariates: Age; Sex; Race/Ethnicity; Education; Current Employment Status; Income; other intermediate factors from model

Analysis: Frequencies; could also look at changes across time using logistic regression (odds ratios, confidence intervals)

EXAMPLE: Awareness of health warning labels on cigarette packages among current smokers			
Characteristic	Wave 1 %	Wave 2 %	Wave 3 %
Age (years)			
12-17			
18-24			
25-44			
45-64			
65 and older			
25 and older			
Sex			
Female			
Male			
Ethnicity			
Not of Hispanic or Latino/ Spanish origin			
Hispanic or Latino/ Spanish origin			
Race			
White			
Black or African American			
American Indian or Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Education			
Less than high school			
Some high school			
High school graduate/GED			
Some college			
Associate degree (occupational/vocational)			
Associate degree (academic program)			
Bachelor's degree			
Graduate degree			
Current employment status			

Don't currently work for pay			
Work part-time (<15 hours/week)			
Work part-time (15-34 hours/week)			
Work full-time (>=35 hours/week)			
Annual Household Income			
Under \$10,000			
\$10,000-\$29,999			
\$30,000-\$44,999			
\$45,000-\$59,999			
\$60,000-\$74,999			
\$75,000-\$99,999			
\$100,000-\$149,999			
\$150,000 and over			

Source: Population Assessment of Tobacco and Health Survey

*p-value<0.05; **p-value<0.01

Sample of Analysis Plan of Larger Pictorial Warning Labels on Cigarettes.

The accompanying conceptual model in Figure 1 guides the analysis plan with respect to this regulatory action. Regulatory action is hypothesized to cause changes in a variety of proximal and distal measures that will ultimately result in changes in smoking cessation, uptake and relapse. The enumerated list below are specific analyses that will be undertaken to examine these various pathways. The parenthetical number in each bullet refers to the numbered box in Figure 1. All potential analyses would include above outlined demographic factors, as well as additional covariates outlined within each outcome

- Awareness of health warning labels among nonusers and former users of tobacco products(1a)
- Knowledge of health warnings among nonusers, former users, and current users (1b)
- Depth of Processing of Message on label among nonusers, former users, and current users (1d)
- Uptake and Positive Beliefs/Product Appeal among nonusers (2)
- Quitting and Positive Beliefs/Product Appeal among current users (2)
- Relapse and Positive Beliefs/Product Appeal among former users (2)
- Uptake and Social norms among nonusers (3)
- Quitting and Social norms among current users (3)
- Relapse and Social norms among former users (3)
- Uptake and Affective reactions among nonusers (4)
- Quitting and Affective reactions among current users (4)
- Relapse and Affective reactions among former users (4)
- Uptake and Cognitive reactions (beliefs about health effects) among nonusers (5a)
- Uptake and Cognitive reactions (thinking/worry about health risks) among nonusers (5b)
- Quitting and Cognitive reactions (beliefs about health effects) among current users (5a)
- Quitting and Cognitive reactions (thinking/worry about health risks) among current users (5b)
- Relapse and Cognitive reactions (beliefs about health effects) among former users (5a)
- Relapse and Cognitive reactions (thinking/worry about health risks) among former users (5b)
- Uptake and Cessation beliefs among nonusers (6)
- Quitting and Cessation beliefs among current users (6)
- Relapse and Cessation beliefs among former users (6)
- Perceived Risk among nonusers, taking into account Salience and Processing (1) and Affective (4) and Cognitive (5) reactions
- Uptake among nonusers taking into account Salience and Processing, Positive Beliefs/Product Appeal (2), Social Norms (3), Perceived Risk (7), and Cessation beliefs (6)
- Perceived Risk from tobacco use (7) among current users, taking into account Salience and Processing (1), Affective Reactions (4), and Cognitive Reactions (5)
- Avoidance of the health warning labels among current users, taking into account Salience and Processing (1), Affective Reactions (4), and Cognitive Reactions (5)

- Quit intentions among current users taking into account Salience and Processing (1), Positive beliefs and product appeal (2), Social Norms (3), Perceived Risk (7), Affective (4) and Cognitive (5) Reactions, and Cessation beliefs (6)
- Use of Cessation Assistance (10) among current users, accounting for quit intentions (9), and Cessation Beliefs (6)
- Smoking behavior changes (11) among current users, including changes in consumption (11a), quit attempts (11b), or abstinence (11c), taking into account quit intentions (9) and use of cessation assistance (10)
- Perceived risk (7) among former users, accounting for salience and processing (1) and affective (4) and cognitive (5) reactions
- Motivation to remain abstinent (9) among former tobacco users, taking into account positive beliefs/product appeal (2), social norms (3), perceived risk (7), and Cessation beliefs (6)
- Use of cessation assistance (10) among former tobacco users, taking into account cessation beliefs (6) and motivation to remain abstinent (9)
- Continued abstinence as smoking behavior (11) among former users, taking into account motivation to remain abstinent (9) and use of cessation assistance (10)
- Relapse among former tobacco users, taking into account motivation to remain abstinent (9)

FIGURE 1. CONCEPTUAL MODEL FOR PACKAGING AND HEALTH WARNING LABELS

