PREDICTIVE AND EXTERNAL VALIDITY OF A PRE-MARKET STUDY TO DETERMINE THE MOST EFFECTIVE PICTORIAL HEALTH WARNING LABEL CONTENT FOR CIGARETTE PACKAGES

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BACKGROUND and OBJECTIVES

Studies examining pictorial health warning label (HWL) content for cigarette packs have primarily used experimental, forced exposure designs with convenience samples, and results from these studies may not predict general population responses under conditions of repeated, naturalistic exposure. This research aimed to determine the predictive and external validity of a pre-market experimental study to assess the efficacy of different pictorial HWL content.

METHODS

Data were analyzed from two sources: 1) a pre-market convenience sample of 544 adult smokers who participated in field experiments conducted in Mexico City between June 2 and August 7, 2010, before pictorial HWLs were first implemented in September 2010; and 2) a population-based representative sample of 1765 adult smokers from seven major Mexican cities who participated in the ITC-Mexico survey after pictorial HWL implementation. Participants in the pre-market sample were randomly assigned to rate the six HWLs that later appeared on Mexican cigarette packs while participants in the post-market sample who remembered having seen the six HWLs rated the warnings. Ratings of the six HWLs were combined into a single effectiveness scale (alpha ranging from 0.79 to 0.90, done for each HWL). Unadjusted and adjusted linear mixed effects models were used to test the relative effectiveness of the six HWLs that appeared on cigarette packs. Participants were also randomly assigned to rank 5 to 7 different HWLs for two of 17 health topics (pre-market sample) or one of 7 health topics (post-market sample) : one text-only warning and multiple pictorial warnings with various representational styles (graphic health effects, lived experience, symbolic images, and testimonials). For the 3 health topics with maximal variation in representational styles (see Table 3), unadjusted and adjusted logistic mixed effects models were estimated to assess which HWL representational styles were given higher impact rankings. For both sets of analyses, mixed effect models adjusted for repeated measures within individuals who evaluated more than one stimulus, and fully adjusted models accounted for sociodemographics, smoking intensity, and quit intention.

RESULTS

Sample Characteristics: Compared to the analytic sample for the post-market study, the analytic sample for the pre-market study included a higher proportion of: males, older people, people with lower educational attainment, daily smokers, and people without quit intention (Table 1).

Six Health Warning Labels: Pre- and post-market data showed similar relative ratings across the six HWLs, with the least and most effective HWLs consistently differentiated from other HWLs (Table 2).

Table 2: Effectiveness scores of the six HWLs on Mexican cigarette packs

Sample	A	B	C	D	E	F
Pre-market	n=62	n=61	n=60	n=62	n=62	n=60
	4.15[a]	5.87[b]	6.18[bc]	6.84[cd]	6.93[cd]	6.99[d]
Post-market	n=700	n=457	n=686	n=822	n=681	n=1184
	7.11[a]	7.17[a]	7.61[b]	7.55[b]	7.62[b]	7.65[c]

Note. Superscript letters denote significant difference at p < 0.05 for all pair wise comparisons. Warnings within the same set with the same superscript letter are not significantly different from one another. Significance remains the same for both unadjusted and adjusted models with covariates, sex, age, educational attainment, smoking intensity and quit intention.

Table 1: Sample demographics and smoking characteristics

Characteristics	Pre-market sample Six HWLs % (n=335)	Pre-market sample HWL styles % (n=167)	Post-market sample Six HWLs % (n=1529)	Post-market sample HWL styles % (n=735)
Sex				
Male	50	52	64	64
Age (mean)	29	28	39	39
Age group				
18-24	44	51	18	18
25-39	40	36	39	39
40-54	12	9	28	27
55+	4	4	15	16
Education				
Low	13	12	62	62
Moderate	47	48	24	24
High	40	40	14	14
Smoke status				
Daily >= 5*	34	35	45	45
Daily < 5*	20	18	29	31
Non-daily	46	47	26	24
Quit intention**				
Yes	25	26	15	14

Note. *Cigarettes per day; **Planning to quit smoking in the next 6 months.

HWL Representational Styles:

HWLs with a variety of representative styles that portray the 3 health topics were analyzed (Table 3). Models comparing text-only HWLs with pictorial HWLs indicated the lesser likelihood of text-only HWLs to be ranked as more effective, although this was statistically significant only in the post-market study (Table 4). In models comparing different pictorial styles of HWLs, HWLs showing lived experiences, both with and without graphic content, outperformed symbolic content, although this difference was statistically significant only in the post-market sample. In both pre- and post-market samples, models indicated that pictorial HWLs with testimonial content were ranked as more effective than didactic content.

Table 3: HWL representational styles

Note. TX, text-only; G, graphic; LE, lived experience; T, testimonial; S, symbolic.

Table 4: Relative effectiveness of HWL representational styles

Sample	Characteristics	Odd Ratios (95% CI) Unadjusted	Odd Ratios (95% CI) Adjusted[a]
Pre-market	Pictorial	1	1
	Text-only	0.77 (0.50, 1.16)	0.76 (0.50, 1.15)
	Symbolic	1	1
	Graphic	1.06 (0.63, 1.81)	0.84 (0.46, 1.53)
	Lived experience	1.21 (0.78, 1.87)	1.05 (0.65, 1.68)
	Graphic with lived experience	1.23 (0.61, 2.50)	1.58 (0.73, 3.41)
	Didactic	1	1
	Testimonial	1.52 (1.00, 2.29)*	1.52 (1.00, 2.29)*
Post-market	Pictorial	1	1
	Text-only	0.19 (0.14, 0.26)***	0.19 (0.14, 0.25)***
	Symbolic	1	1
	Graphic	1.11 (0.83, 1.48)	1.00 (0.73, 1.38)
	Lived experience	1.57 (1.23, 2.00)***	1.48 (1.15, 1.92)***
	Graphic with lived experience	2.47 (1.71, 3.58)***	2.65 (1.80, 3.90)***
	Didactic	1	1
	Testimonial	2.41 (1.95, 2.97)***	2.37 (1.92, 2.93)***

Note. [a]Adjusted for sex, age, educational attainment, smoking intensity and quit intention. *p<.05; **p<.01; ***p<.001

CONCLUSIONS

Smokers' evaluations of the six HWLs that were included in the first round of pictorial HWLs were generally consistent across pre- and post-market studies, suggesting the predictive validity of the pre-market study. Pre-market study results for HWL styles found statistically significant differences between HWL stimuli only when comparing testimonial and didactic content. However, statistically significant differences between HWLs in the post-market study were consistent with results from the larger parent pre-market study,[1] which had more variation in stimuli (17 topics), included a rating scale, and had a larger sample size and statistical power to determine effects. Overall, our study suggests that well-designed pre-market studies can have predictive and external validity, helping regulators select HWL content.

Reference: 1. Hammond D, Thrasher JF, Reid JL, Driezen, Boudreau C, Santillan EA. (2012). Perceived effectiveness of pictorial health warnings among Mexican youth and adults: a population-level intervention with potential to reduce tobacco-related inequities. Cancer Causes Control. 23: 57-67.

Conflicts of Interest: None.