The impact of the 2009/2010 enhancement of cigarette health warning labels in Uruguay: longitudinal findings from the International Tobacco Control (ITC) Uruguay Survey

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ABSTRACT

Background Framework Convention on Tobacco Control (FCTC) Article 11 Guidelines recommend that health warning labels (HWLs) should occupy at least 50% of the package, but the tobacco industry claims that increasing the size would not lead to further benefits. This article reports the first population study to examine the impact of increasing HWL size above 50%. We tested the hypothesis that the 2009/2010 enhancement of the HWLs in Uruguay would be associated with higher levels of effectiveness.

Methods Data were drawn from a cohort of adult smokers (≥18 years) participating in the International Tobacco Control (ITC) Uruguay Survey. The probability sample cohort was representative of adult smokers in five cities. The surveys included key indicators of HWL effectiveness. Data were collected in 2008/09 (prepolicy: wave 2) and 2010/11 (postpolicy: wave 3).

Results Overall, 1746 smokers participated in the study at wave 2 (n=1379) and wave 3 (n=1411). Following the 2009/2010 HWL changes in Uruguay (from 50% to 80% in size), all indicators of HWL effectiveness increased significantly (noticing HWLs: OR=1.44, p=0.015; reading HWLs: OR=1.42, p=0.002; impact of HWLs on thinking about risks of smoking: OR=1.66, p<0.001; HWLs increasing thinking about quitting: OR=1.76, p<0.001; avoiding looking at the HWLs: OR=2.35, p<0.001; and reports that HWLs stopped smokers from having a cigarette 'many times': OR=3.42, p<0.001).

Conclusions The 2009/2010 changes to HWLs in Uruguay, including a substantial increment in size, led to increases of key HWL indicators, thus supporting the conclusion that enhancing HWLs beyond minimum guideline recommendations can lead to even higher levels of effectiveness.

BACKGROUND

Health warning labels (HWLs) play a key role among policies of the WHO Framework Convention on Tobacco Control (FCTC) because of their demonstrated effectiveness in informing consumers about the harms of tobacco products. Although HWLs are an important source of information about the harms of smoking, the extent to which people read, think about and act on the HWLs depends on the size, position, content and design of these messages. ^{1 2}

Indeed, conceptual work and empirical studies have both identified key indicators of HWL effectiveness, which have been employed in a wide range of studies across different countries. 1-4 These studies have demonstrated the predictive validity of these key indicators. For example, in comparison with smaller, text-only HWLs, larger HWLs with pictures are more effective because they are more likely to: be noticed, provoke thoughts of quitting smoking, increase knowledge of the health risks associated with smoking, decrease the demand for cigarettes, motivate smokers to forego cigarettes, reduce smoking, prevent relapse among adults 1 2 4-6 and help to prevent smoking initiation among youth.^{2 7 8} Moreover, replacing tobacco branding on packaging with larger pictorial HWLs diminishes the attractiveness of the product, particularly among vulnerable adolescents.

Although the majority of the studies that have demonstrated the positive effects of larger picture HWLs have been conducted in high income countries (HICs), similar results have also been found for non-Western and/or low and middle income countries (LMICs), ¹ 10-13 demonstrating that the benefits of large pictorial HWLs are not limited to HICs.

Smoking and tobacco control in Uruguay

Smoking rates are high in many regions of Latin America, including Uruguay. 14 In 2009, the smoking rate in Uruguay among those aged 15+ years was 25% (30.7% of men and 19.8% of women). 14 In order to address these high smoking rates, Uruguay became a Party to the WHO FCTC on 9 September 2004, and since then has implemented several strong tobacco control policies in several of the FCTC domains. Specifically, Uruguay addressed Article 11 Guidelines of the FCTC, which states that each Party shall adopt and implement effective packaging and labelling measures. 15 In brief, the Article 11 Implementation Guidelines, which were adopted in November 2008, are explicit about their recommendation about the size of HWLs: "Parties should consider using HWLs and messages that cover more than 50% of the principal display areas, and aim to cover as much of the principal display areas as possible."¹⁵ The tobacco industry has claimed that 50% represents the point at which maximal impact is achieved and that larger HWLs would not lead to an increased



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benefit. ¹⁶ ¹⁷ The question of whether increasing the size of HWLs above the FCTC minimum recommendation of 50% leads to an increase in effectiveness has not yet, to our knowledge, been explicitly addressed in population studies. The evolution of pictorial HWLs in Uruguay provided an opportunity for such a study.

Pictorial health warning labels in Uruguay

Uruguay was the eighth country in the world to require pictorial HWLs, beginning in April 2006. These first set of labels consisted of eight HWLs that occupied 50% of the front and back of the pack (Round 1). In February 2008, three new HWLs were introduced (Round 2). The Round 1 and Round 2 HWLs used symbolic images (eg, cigarettes as prison bars, tombstones) to depict death and diseases caused by cigarettes. In February 2009, eight new 50% HWLs were introduced (Round 3), which used more graphic, emotionally evocative imagery (eg, a child with a mask to depict the hazard of secondhand smoke). In December 2009, a law was enacted that increased the HWLs to 80% of the front and back of the pack and six new graphic HWLs of this size were introduced in February 2010 (Round 4). The HWLs on the front of the pack were, as of April 2014, the largest in the world.

The current study addresses the impact of increasing pictorial HWL size using data from two waves of the International Tobacco Control (ITC) Uruguay Survey. Specifically, we examined whether the change in the Uruguay HWLs in 2009/2010, including the increase in size from the recommended 50% of the FCTC Article 11 Guidelines to 80%, led to increases in key HWL effectiveness indicators: (1) salience (noticeability, reading) of HWLs; (2) frequency of thoughts about smoking-related harms and about quitting because of HWLs and (3) foregoing cigarettes because of HWLs. We also examined the possibility that quitters would be more likely to mention the HWLs as a reason for quitting at the postpolicy wave compared with the prepolicy wave.

METHODS

Sample design and procedure

The ITC Uruguay Survey is a prospective longitudinal cohort study of adult smokers. The wave 1 Survey was conducted in the Uruguayan capital of Montevideo during November–December 2006. The wave 2 Survey, conducted between October 2008 and February 2009, added the inland cities of Durazno, Maldonado, Rivera and Salto.

In each city, a stratified multistage sampling design was used, with the primary strata corresponding to census tracts. In Montevideo, the study sample at wave 2 consisted of two groups: cohort respondents from wave 1 and new respondents, randomly selected from the same sampling frame, to replace those wave 1 respondents who had been lost to attrition.

At wave 2, respondents from the four inland cities were all new respondents. The study sample at wave 3, conducted between October 2010 and January 2011, included a combination of cohort and replenishment respondents from all five cities. Further details on the sampling methodology are available on the ITC Project website (wave 1: http://www.itcproject.org/files/Report_Publications/Technical_Report/itcuruguayw1techrepfinalmar08.pdf; Waves 2 and 3: http://www.itcproject.org/files/ITC_UY_2-3_Technical_Report final (14-Jan-13).pdf).

Study sample

At initial recruitment, respondents were adult smokers (≥18 years old) who reported having smoked at least 100 cigarettes and who had smoked at least 1 cigarette in the past week. All participants

were surveyed using face-to-face interviews. The survey fieldwork was conducted in Spanish by 60 trained interviewers from the Tobacco Epidemic Research Center, based in Montevideo. Interviews were conducted individually with up to two participants in each household, one male and one female smoker. The length of the survey interview was 50–55 min for smokers and 30–35 min for those who had quit at Waves 2 and 3.

Response rates at each wave can be found in the ITC Uruguay technical reports (details provided above). In brief, the wave 2 Survey sample consisted of 1379 respondents: 585 cohort (respondents from wave 1) and 392 replenishment (n=977) in Montevideo (retention rate of 66.0%), and 402 newly recruited respondents from inland cities, using a quota of 100 in each city. The wave 3 sample consisted of 1411 respondents: 971 cohort and 440 replenishment (retention rate of 70.4%). The wave 2 and wave 3 individual response rates for newly recruited (including replenishment) individuals were 78.2% and 72.4%, respectively. Overall, 1746 unique smoking individuals participated at Waves 2 and 3. Table 1 displays the respondent demographic characteristics and smoking behaviours at Waves 2 and 3 as well as the total sample of individual cases.

Measure

Demographics and smoking-relevant variables

Sociodemographic characteristics were assessed with standard questions on sex, age, marital status, highest educational attainment and monthly household family income (in Uruguayan Pesos; 1 Peso=US\$0.046). A 3-category variable was created for educational attainment (low=< high school, moderate=high school or technical school, and high=university or equivalent) and a fourcategory variable was created for income levels (low=≤\$7000, moderate=\$7001-30 000, high=>\$30 001, missing values=not reported).

Smoking-relevant variables consisted of: smoking frequency (daily, non-daily or quitter), previous quit attempts (ever tried to quit in the past, even if just once, vs never having tried to make an attempt to quit smoking), and number of cigarettes smoked per day (categorised as 1–10, 11–20, 21–30 and \geq 31). To be considered 'quit smoking', the respondent indicated that they had stopped smoking.

Health warning effectiveness measures

Health warning *salience* (noticing and reading the warnings closely) was assessed with two questions: "In the last month, how often have you noticed the health warnings on cigarette packages?" and "In the last month, how often have you read or looked closely at the health warnings on cigarette packages?" The response options for both were 'Never', 'Once in a while', 'Often' and 'Very often'.

Cognitive reactions to the warnings (thoughts about the harms of smoking and thoughts about quitting) were assessed using the following two questions: "To what extent do the health warnings make you think about the dangers from smoking?" (thoughts about harms of smoking attributed to the warnings) and "To what extent do the health warnings on cigarette packs make you think about quitting smoking?" (thoughts about quitting attributed to the warnings) with response options 'Not at all', 'A little', 'Somewhat' and 'A lot'.

Behavioural reactions to the warnings (foregoing of cigarettes and avoidance) were assessed by asking: "In the last month, have the health warnings stopped you from having a cigarette when you were about to smoke one?" (foregoing of cigarette attributed to the warnings; response options: 'Never', 'Once', 'A few times' and 'Many times') and "In the last month, have

Respondent demographic characteristics and smoking behaviours

Characteristic	Wave 2 n=1379			Wave 3 n=1411			
	Montevideo n=977	Inland Cities n=402	p Value	Montevideo n=1007	Inland Cities n=404	p Value	Total sample N=1746
Wave							
2	-	-	-	-	-	-	1294 (74.1)
3	_	-	_	-	-	-	452 (25.9)
Sex, n (%)							
Male	454 (46.5)	221 (55.7)	0.002	474 (47.1)	218 (54.0)	0.010	849 (48.6)
Female	523 (53.5)	181 (44.3)		533 (52.9)	186 (46.0)		897 (51.4)
Age group, n (%)							
18–24	191 (19.6)	73 (18.2)	0.800	166 (16.5)	68 (16.8)	0.910	311 (17.8)
25–39	309 (31.6)	139 (34.6)		340 (33.8)	130 (32.2)		578 (33.1)
40-54	294 (30.1)	117 (29.1)		305 (30.3)	130 (32.2)		528 (30.2)
55+	183 (18.7)	73 (18.2)		196 (19.5)	76 (18.8)		329 (18.9)
Education, n (%)	` ,	, ,		` '	, ,		, ,
Low	549 (56.3)	287 (71.4)	< 0.0001	534 (53.0)	243 (60.2)	0.002	1039 (59.6)
Moderate	236 (24.2)	73 (18.2)		250 (24.8)	114 (28.2)		391 (22.4)
High	190 (19.5)	42 (10.4)		223 (22.2)	47 (11.6)		314 (18.0)
Marital status, n (%		(,		,	(,		(,
Married	370 (37.9)	162 (40.3)	0.476	371 (36.8)	157 (38.9)	0.542	626 (35.9)
Other	607 (62.1)	240 (59.7)		636 (63.2)	247 (61.4)		1120 (64.1)
Income, n (%)	(,	(,		(,	(,		(,
Low	313 (32.7)	198 (50.1)	< 0.0001	174 (17.3)	120 (29.7)	< 0.0001	555 (32.5)
Moderate	467 (48.8)	166 (42.0)		536 (53.2)	192 (47.5)		822 (48.2)
High	104 (9.0)	14 (2.5)		195 (19.4)	39 (9.7)		156 (9.2)
NS	92 (9.6)	21 (5.3)		102 (10.1)	53 (13.1)		172 (10.1)
Employment, n (%)		21 (3.3)		102 (10.1)	55 (15.1)		172 (10.1)
FT FT	504 (51.8)	171 (42.5)	0.004	453 (45.0)	183 (45.3)	0.927	827 (47.5)
Other	469 (48.2)	231 (57.5)	0.004	553 (55.0)	221 (54.7)	0.527	915 (52.5)
Smoking frequency,		251 (57.5)		333 (33.0)	221 (54.7)		313 (32.3)
Daily	811 (83.0)	368 (91.5)	<0.0001	798 (79.2)	312 (77.8)	0.700	1588 (90.9)
Non-daily	81 (8.2)	34 (8.5)	\0.0001	78 (7.8)	36 (9.0)	0.700	158 (9.1)
Quit	85 (8.7)	0 (0.00)		131 (13.0)	56 (13.9)		136 (3.1)
Previous quit attem		0 (0.00)		151 (15.0)	50 (15.9)		_
Yes	pts, 11 (%) 715 (73.2)	283 (70.4)	0.349	700 (70 2)	326 (90.7)	0.304	1220 /70 0\
		283 (70.4)	0.349	788 (78.3)	326 (80.7)	0.304	1238 (70.9)
No attempt Cigarettes/day, n (%	262 (26.8)	119 (29.6)		219 (21.7)	78 (19.3)		508 (29.1)
		221 (57.6)	-0.0001	A1E (A7 O)	104 (FF O)	0.021	OFF (40.1)
1–10	395 (44.3)	231 (57.6)	<0.0001	415 (47.8)	194 (55.9)	0.031	855 (49.1)
11–20	362 (40.6)	133 (33.2)		330 (38.0)	119 (34.3)		654 (37.5)
21–30	76 (8.5)	17 (4.2)		61 (7.0)	21 (6.0)		124 (7.1)
≥31	58 (6.5)	20 (5.0)		63 (7.2)	13 (3.8)		109 (6.3)

Total number of unique cases in Waves 2 and 3 that are smokers only.

FT. full-time: NS. not stated.

you made any effort to avoid looking at or thinking about the health warnings?" (Yes/No; avoidance of warnings).

Respondents were also asked: "Do you think that cigarette packages should have more health information than they do now, less, or about the same amount as they do now?" with response options: 'Less health information', 'About the same' and 'More health information'. This variable was dichotomised into "less/about the same amount of health information" versus "more health information".

Those who quit smoking were asked: "Did warning labels on cigarette packages lead you to quit smoking?" with response options: 'not at all', 'somewhat' or 'very much'. These responses were dichotomised into 'not at all' versus 'somewhat/very much'.

Time-in-sample

In longitudinal surveys, individuals' responses may differ as a function of the number of previous waves in which they have participated. The analyses controlled for these time-in-sample (TIS) effects by adding to all analytic models a TIS variable of which the value was equal to the number of waves that the respondent had completed before. Methodological details are presented elsewhere. 18

Statistical analyses

To test whether the introduction of the new pictorial HWLs increased salience of the labels (noticing and reading), and psychological and behavioural reactions to the labels (thinking

p Values estimate characteristic differences between Montevideo and Inland city residents.

Some characteristics have missing values if they were not reported at time of entry into the study (percentages take into account missing data).

Results are unweighted but the survey design was accounted for in the analysis. All tests are the Rao-Scott χ^2 test unless otherwise indicated. Previous quit attempts: ever tried to quit in the past, even if just once, versus never having tried to make an attempt to quit smoking.

about the risks, thoughts of quitting, avoiding labels and foregoing a cigarette), the proportion of smokers responding in the affirmative for each measure was estimated for the prepolicy wave (wave 2) and the postpolicy wave (wave 3).

Initial unweighted descriptive statistics were used to describe demographic and smoking characteristics of respondents by wave and city (Montevideo vs Inland cities), and differences by respondent type (cohort respondents, those lost to attrition and replenishment). Rao-Scott χ^2 tests were conducted to test for differences between respondents by their city of recruitment. A description of the total sample (N=1746) is also presented.

For each outcome measure, logistic regression generalised estimated equations (GEEs) were used to test differences between the prepolicy and postpolicy surveys. All GEE models were estimated using an exchangeable working correlation structure. Unadjusted and adjusted GEE analyses were conducted among quitters to test for differences between prepolicy and postpolicy waves on whether HWLs led them to quit smoking.

The analyses were conducted using SUDAAN V.10.0.1, which controlled for the multistage sampling design (clustering of survey respondents within primary sampling units) and the longitudinal design. All regression models adjusted for sex (male or female), age group (18–24, 25–39, 40–54 or 55+ years), smoking status (daily or non-daily), city (Montevideo or Inland cities), education (low, moderate or high), income (low, moderate or high) and TIS. People who no longer smoked at the time of the survey were excluded from the main analyses. Unless otherwise stated, all results were weighted, with SEs and model coefficients adjusted accordingly.

RESULTS

Prepolicy and postpolicy sample differences

Data from the previous wave were used for those lost to attrition. Initial unweighted analyses showed that respondents lost to attrition at the postpolicy wave were less likely to be making a moderate income or to report their income (p=0.011), less likely to be married (p=0.037) and more likely to avoid HWLs compared with other prepolicy respondents (p=0.037).

The newly recruited sample at wave 3 was less likely to be in the lower income bracket (15.9%) versus cohort respondents (38.1%) and those lost to attrition (35.8%, p<0.001). Table 2 shows the characteristics of sampled respondents by respondent type.

Respondent characteristics

Table 1 presents the demographic and smoking behaviour characteristics of the sample. Overall, wave 2 (prepolicy) included 1379 respondents and wave 3 included 1411 respondents. At wave 2, compared with Montevideo participants, a greater proportion of inland city respondents were male, less educated, had low income and did not work full-time. Although inland respondents were more likely to be daily smokers, they also tended to smoke fewer cigarettes per day. Similar differences were observed in wave 3 (postpolicy).

There were minor differences among respondent characteristics between wave 2 and wave 3 (see online supplementary data table). At wave 3, fewer respondents were in the low income group, slightly more were employed full-time and more had tried to quit smoking on at least one occasion.

Current smokers were included in the main analyses. Smokers who indicated that they had quit were eliminated at that wave. Overall, 1746 unique smoking individuals participated in the study at Waves 2 and 3. Among these respondents, 51% were women, 60% had a low education, 50% had a moderate income, 91% were daily smokers and 49% smoked 1–10

cigarettes per day. Nearly 70% of respondents had ever tried to quit smoking.

Smokers' responses to the enhanced HWLs

Table 3 presents the adjusted estimates and results from the GEE analysis, which examined how the indicators of HWL effectiveness changed after the introduction of the enhanced HWLs.

Controlling for the covariates, all measures of HWL effectiveness increased significantly at the postpolicy wave: noticing HWLs often or very often (64.5–72.3%; OR=1.44, p=0.015), reading HWLs closely often or very often (40.5–49.2%; OR=1.42, p=0.002), thinking about the risks of smoking somewhat or a lot (31.5–43.3%; OR=1.66, p<0.001), thinking about quitting somewhat or a lot (20.6–31.3%; OR=1.76, p<0.001), avoiding HWLs (12.1–24.4%; OR=2.35, OR=1.76, and foregoing a cigarette many times because of the HWLs (1.9–6.1%; OR=3.42, OR

There were no differences between the percentage of smokers who thought that packs should have more information (vs less/the same) between prepolicy (28.3%) and postpolicy (28.8%, p=0.86). Thus, the percentage of smokers wanting more information had not diminished despite the increased effectiveness of the HWLs.

Quitters' responses to the enhanced HWLs

There were 225 unique respondents who reported having quit when surveyed at either the prepolicy or postpolicy survey (44 people had quit at both waves, 41 at wave 2 only and 140 at wave 3 only). The percentage of quitters who reported that HWLs led them to quit smoking was 23.5% at the prepolicy survey and 38.7% at the postpolicy survey. In the adjusted GEE model, the prepolicy and postpolicy assessments were not significantly different from one another (p=0.26), which is not surprising given the low sample sizes.

DISCUSSION

The present study, to the best of our knowledge, is the first population study to measure the impact of increasing the size of the HWLs above the minimum recommended size of 50% of the FCTC Article 11 Guidelines. The 2009/2010 introduction of larger and more graphic HWLs in Uruguay-from 50% to 80%—were associated with significant increases in all of the key indicators of HWL effectiveness. The pattern of results thus supports the recommendations of the FCTC Article 11 Guidelines for Parties to use the HWLs "to cover as much of the principal display areas as possible,"15 and argues against the tobacco industry's claims that 50% HWLs are sufficient and that larger HWLs would not lead to greater effectiveness. In fact, because the size of a HWL is positively related to its salience,^{2 3} it makes little sense to claim that 50% would be the point at which maximal impact would be achieved. This would seem to be particularly true for tobacco HWLs, which have a dual effect on communicating health messages and also reducing the area that is used for branding.¹⁹

These population-based findings are consistent with experimental studies that have shown that larger HWLs are more effective in discouraging people from smoking, in provoking thoughts of quitting and in conveying the health risks of smoking.^{2 7 8 20-23} Moreover, the present findings are consistent with experimental and observational studies, which have both shown that HWLs with larger graphic pictures are more effective than smaller, less graphic or text-only HWLs for key HWL indicators. Indeed, a large and growing body of evidence

Table 2 Characteristics of sampled respondents by respondent type

	Retained cohort		Lost at Wave 3		Replenishment sample				
	n	Per cent	n	Per cent	n	Per cent	χ^2	df	p Value
Sex									
Male	380	49.2	252	47.2	217	49.3	0.80	2	0.672
Female	392	50.8	282	52.8	223	50.7			
Age group									
18–24	132	17.1	115	21.5	64	14.5	9.01	6	0.173
25–39	263	34.1	168	31.5	147	33.4			
40–54	240	31.1	150	28.1	138	31.4			
55+	137	17.7	101	18.9	91	20.7			
Income									
Low	294	38.1	191	35.8	70	15.9	76.06	6	< 0.001
Moderate	369	47.8	230	43.1	223	50.7			
High	53	6.9	48	9.0	70	15.9			
Not reported	56	7.3	65	12.2	77	17.5			
Education									
Low	474	61.5	325	61.0	240	54.5	8.59	4	0.072
Moderate	178	23.1	107	20.1	106	24.1			
High	119	15.4	101	18.9	94	21.4			
Marital status									
Not married	456	59.1	347	65.0	317	72.0	19.79	2	< 0.001
Married	316	40.9	187	35.0	123	28.0			
Employment status									
Not working full-time	385	49.9	247	46.5	195	44.3	4.12	2	0.128
Working full-time	386	50.1	284	53.5	245	55.7			
Daily smoker									
Non-daily smoker	61	7.9	56	10.5	41	9.3	2.26	2	0.323
Daily smoker	711	92.1	478	89.5	399	90.7			
Previous quit attempt									
Never tried to quit	232	30.1	152	28.5	127	28.9	0.38	2	0.826
Tried to quit at least once	540	69.9	382	71.5	313	71.1			
Cigarettes/day									
1–10	359	46.5	276	51.9	220	50.2	6.06	6	0.416
11–20	301	39.0	197	37.0	156	35.6			
21–30	60	7.8	33	6.2	31	7.1			
31+	52	6.7	26	4.9	31	7.1			

Results are unweighted, but the survey design was accounted for in the analysis. Rao-Scott χ^2 tests were used to compare differences between respondent types.

confirms that comprehensive HWLs can promote cessation behaviour and discourage initiation, and that larger pictorial HWLs are most effective in doing so.^{2 3 8 20 24 25} These findings in Uruguay thus add to the growing number of studies in LMICs showing the benefits of large, pictorial HWLs.

Limitations

Although the size of the Uruguayan HWLs increased significantly from 50% to 80% between the two survey waves, the pictorial images also became more graphic. It has been shown that pictorial HWLs with graphic depictions of disease have been rated as more effective than symbolic pictorial HWLs. Thus the substantial increases in all indicators of HWL effectiveness cannot be attributed to the increased size alone. Also, it may be the case that some of the effects of the HWL are due to novelty effects as we did not analyse whether the changes were sustained over time.

Finally, while we recognise that there were differences between the sample respondent types in our cohort design, any differences would be roughly the same over the two waves and thus would be unlikely to explain differences in effectiveness that were found in this study. Empirical evidence has shown that income is not related strongly to HWL outcomes, and that other variables such as education and smoking intensity (thus affecting exposure to HWLs) matter most. ² ⁶ ^{10–12} ²⁶ ^{28–30} Perhaps the most important variables —education, intensity of smoking (cigarettes per day) and type of smoker (daily/non-daily)—were not significantly different, which is reassuring considering they would likely have had more effect on the outcomes (eg, smoking intensity would be positively related to exposure to the HWLs). Moreover, the difference in income between prepolicy and postpolicy respondents would not have biased the results as income was controlled for in HWL analyses. With regard to previous quit attempts difference, considering that there was a large proportion of smokers present in wave 3 who were present in wave 2, it would certainly be reasonable to expect that they would naturally try to quit over time.

In conclusion, these findings support the FCTC Article 11 Guidelines stating that the 50% HWL size should be considered a minimum standard; and there is no reason to believe that this general principle would be limited to HICs, given the results of

Table 3 Adjusted estimates and generalised estimated equation analysis examining differences in health warning labels on salience, perceptions and behaviour between prepolicy (wave 2) and postpolicy (wave 3)

Wave 2 (prepolicy)		Wave 3 (postpolicy)			Difference between wave 3 and wave 2			
Per cent	(95% CI)	Per cent	(95% CI)	OR	(95% CI)	Wald χ^2	df	p Value
64.5	(59.6 to 69.5)	72.3	(68.4 to 76.3)	1.44	(1.07 to 1.93)	5.97	1	0.015
40.5	(35.9 to 45.2)	49.2	(45.2 to 53.2)	1.42	(1.13 to 1.79)	9.19	1	0.002
31.5	(27.4 to 35.6)	43.3	(38.5 to 48.1)	1.66	(1.27 to 2.19)	13.50	1	< 0.001
20.6	(17.3 to 23.9)	31.3	(27.5 to 35.0)	1.76	(1.34 to 2.29)	17.18	1	< 0.001
12.1	(9.3 to 14.8)	24.4	(20.2 to 28.5)	2.35	(1.65 to 3.34)	22.46	1	< 0.001
1.9	(1.0 to 2.8)	6.1	(4.1 to 8.2)	3.42	(1.77 to 6.59)	13.56	1	< 0.001
28.3	(24.3 to 32.4)	28.8	(24.6 to 33.0)	1.03	(0.77 to 1.36)	0.03	1	0.864
	Per cent 64.5 40.5 31.5 20.6 12.1 1.9	Per cent (95% CI) 64.5 (59.6 to 69.5) 40.5 (35.9 to 45.2) 31.5 (27.4 to 35.6) 20.6 (17.3 to 23.9) 12.1 (9.3 to 14.8) 1.9 (1.0 to 2.8)	Per cent (95% CI) Per cent 64.5 (59.6 to 69.5) 72.3 40.5 (35.9 to 45.2) 49.2 31.5 (27.4 to 35.6) 43.3 20.6 (17.3 to 23.9) 31.3 12.1 (9.3 to 14.8) 24.4 1.9 (1.0 to 2.8) 6.1	Per cent (95% CI) Per cent (95% CI) 64.5 (59.6 to 69.5) 72.3 (68.4 to 76.3) 40.5 (35.9 to 45.2) 49.2 (45.2 to 53.2) 31.5 (27.4 to 35.6) 43.3 (38.5 to 48.1) 20.6 (17.3 to 23.9) 31.3 (27.5 to 35.0) 12.1 (9.3 to 14.8) 24.4 (20.2 to 28.5) 1.9 (1.0 to 2.8) 6.1 (4.1 to 8.2)	Per cent (95% CI) Per cent (95% CI) OR 64.5 (59.6 to 69.5) 72.3 (68.4 to 76.3) 1.44 40.5 (35.9 to 45.2) 49.2 (45.2 to 53.2) 1.42 31.5 (27.4 to 35.6) 43.3 (38.5 to 48.1) 1.66 20.6 (17.3 to 23.9) 31.3 (27.5 to 35.0) 1.76 12.1 (9.3 to 14.8) 24.4 (20.2 to 28.5) 2.35 1.9 (1.0 to 2.8) 6.1 (4.1 to 8.2) 3.42	Wave 2 (prepolicy) Wave 3 (postpolicy) wave 2 Per cent (95% CI) Per cent (95% CI) OR (95% CI) 64.5 (59.6 to 69.5) 72.3 (68.4 to 76.3) 1.44 (1.07 to 1.93) 40.5 (35.9 to 45.2) 49.2 (45.2 to 53.2) 1.42 (1.13 to 1.79) 31.5 (27.4 to 35.6) 43.3 (38.5 to 48.1) 1.66 (1.27 to 2.19) 20.6 (17.3 to 23.9) 31.3 (27.5 to 35.0) 1.76 (1.34 to 2.29) 12.1 (9.3 to 14.8) 24.4 (20.2 to 28.5) 2.35 (1.65 to 3.34) 1.9 (1.0 to 2.8) 6.1 (4.1 to 8.2) 3.42 (1.77 to 6.59)	Wave 2 (prepolicy) Wave 3 (postpolicy) wave 2 Per cent (95% CI) Per cent (95% CI) OR (95% CI) Wald χ² 64.5 (59.6 to 69.5) 72.3 (68.4 to 76.3) 1.44 (1.07 to 1.93) 5.97 40.5 (35.9 to 45.2) 49.2 (45.2 to 53.2) 1.42 (1.13 to 1.79) 9.19 31.5 (27.4 to 35.6) 43.3 (38.5 to 48.1) 1.66 (1.27 to 2.19) 13.50 20.6 (17.3 to 23.9) 31.3 (27.5 to 35.0) 1.76 (1.34 to 2.29) 17.18 12.1 (9.3 to 14.8) 24.4 (20.2 to 28.5) 2.35 (1.65 to 3.34) 22.46 1.9 (1.0 to 2.8) 6.1 (4.1 to 8.2) 3.42 (1.77 to 6.59) 13.56	Wave 2 (prepolicy) Wave 3 (postpolicy) wave 2 Per cent (95% CI) Per cent (95% CI) OR (95% CI) Wald χ² df 64.5 (59.6 to 69.5) 72.3 (68.4 to 76.3) 1.44 (1.07 to 1.93) 5.97 1 40.5 (35.9 to 45.2) 49.2 (45.2 to 53.2) 1.42 (1.13 to 1.79) 9.19 1 31.5 (27.4 to 35.6) 43.3 (38.5 to 48.1) 1.66 (1.27 to 2.19) 13.50 1 20.6 (17.3 to 23.9) 31.3 (27.5 to 35.0) 1.76 (1.34 to 2.29) 17.18 1 12.1 (9.3 to 14.8) 24.4 (20.2 to 28.5) 2.35 (1.65 to 3.34) 22.46 1 1.9 (1.0 to 2.8) 6.1 (4.1 to 8.2) 3.42 (1.77 to 6.59) 13.56 1

the present study in Uruguay. Countries that increase the HWL size above 50% would increase effectiveness of their HWLs across a broad range of key outcomes. Given the extremely high exposure that smokers have to the HWLs (up to 7300 exposures every year for a pack-a-day smoker just by taking a cigarette from the pack to smoke) this conclusion points to the potential power and value of implementing large HWLs such as the 80% HWLs in Uruguay.

What this paper adds

- ▶ The Framework Convention on Tobacco Control (FCTC)
 Article 11 Guidelines call for Parties to implement health
 warning labels (HWLs) that are pictorial and occupy at least
 50% of the principal surfaces of the pack. The tobacco
 industry has claimed that there is no evidence that HWLs
 larger than 50% are more effective. Although experimental
 studies demonstrate that HWLs larger than 50% are indeed
 more effective, the present study is the first to examine this
 question in a population-based evaluation study.
- ➤ This study shows that the 2009/2010 changes to the HWLs in Uruguay—including a size increase from 50% to 80% and more graphic images—were associated with significant increases in all key indicators of warning effectiveness, indicators that have been shown to predict future quit attempts.
- ▶ These findings support the recommendation in the Article 11 Guidelines that the 50% HWL size should be considered a minimum standard: countries that increase HWL size beyond 50% would increase the effectiveness of their HWLs across a broad range of key outcomes.

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Competing interests None.

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Data sharing statement Two years after the date of issuance of cleaned data sets, the non-exclusive right to provide subsets of the data to other approved researchers through the ITC Data Request Application process (http://www.itcproject.org/datarequ) and under the terms of the ITC External Data Usage Agreement, access may be granted (http://www.itcproject.org/datarequ).

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