

Published in final edited form as:

*Soc Sci Med.* 2015 January ; 124: 241–245. doi:10.1016/j.socscimed.2014.11.054.

## Implementation of effective cigarette health warning labels among low and middle income countries: State capacity, path-dependency and tobacco industry activity

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### Abstract

We investigate the effects of ratifying the WHO Framework Convention of Tobacco Control (FCTC), state capacity, path-dependency and tobacco industry activity on the implementation of effective health warning labels (HWL) on cigarette packs among low and middle income countries (LMIC). Using logistic regression in separate analyses for FCTC Article 11 compliant HWLs and graphic HWLs (GHWL), we found that the odds of FCTC compliance increased by a factor of 1.31 for each year after FCTC entered into force in the country ( $p < 0.01$ ). The odds of passing GHWLs increased by a factor of 1.46 ( $p < 0.05$ ) per year after FCTC entered into force. The weaker the capacity of the states were, the less likely they were to have implemented FCTC compliant HWLs ( $p < 0.05$ ). The countries with voluntary HWLs in 1992 were less likely (OR = 0.19,  $p < 0.01$ ) to comply with FCTC 21 years later (in 2013). The FCTC has promoted HWL policies among LMICs. Public health regulations require investments in broader state capacity. As the theory of path-dependency predicts voluntary agreements have long lasting influence on the direction of tobacco control in a country. Adopting voluntary HWL policies reduced likelihood of having FCTC compliant HWLs decades later. The fact that voluntary agreements delayed effective tobacco regulations suggests that policymakers must be careful of accepting industry efforts for voluntary agreements in other areas of public health as well, such as alcohol and junk food.

### Keywords

Global tobacco control; health warning labels; FCTC; state fragility

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#### Competing Interests

HH served as an expert witness for a plaintiff in tobacco litigation *Salminen v. Amer Sports Oyj and BAT Finland* in 2008 and in 2009. SAG has nothing to disclose.

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## INTRODUCTION

Tobacco use kills 5.4 million people annually, more than HIV/AIDS, malaria and tuberculosis combined. If current trends continue, tobacco-induced mortality will reach 8.3 million by 2030, with 80% of deaths in developing countries (World Health Organization, 2011). Health warning labels (HWLs) on cigarette packs are a low cost, effective policy to decrease tobacco consumption and mortality (Hammond, 2011). HWLs with graphic elements (GHWLs), first introduced in 1985 (Hiilamo, Crosbie, & Glantz, 2012; World Health Organization, 2011) and which started to spread in the early 2000s, are even more effective than text-only warnings (Aftab, Kolben, & Lurie, 1999; Canadian Cancer Society, 2012; Hammond, 2011; Hammond, Fong, Borland, Cummings, McNeill, & Driezen, 2007; Nascimento, Oliveira, Vieira, Joffily, Gleiser, Pereira et al., 2008; Thrasher, Hammond, Fong, & Arillo-Santillan, 2007), especially in countries with low illiteracy or where several languages are spoken (Hammond et al., 2007). The World Health Organization (WHO) Framework Convention on Tobacco Control (World Health Organization, 2003) (FCTC) accelerated diffusion of HWLs (Sanders-Jackson, Song, Hiilamo, & Glantz). FCTC Article 11 calls for signatories to mandate HWLs with specific health warnings that appear on individual packages and any outside packaging and retail sale labeling. The HWL should describe specific harmful effects of tobacco use on health and they should cover at least 30% of the package's external surface area. The HWLs must be written in all principal languages and they must rotate. The HWLs may also include pictures or pictograms (FCTC/COP3(10)), 2008). In force since early 2005, 176 parties had ratified the FCTC by May 2013. The FCTC gives newly-ratifying parties three years to comply with Article 11.

The theory of path-dependency, one of the major theories explaining institutional change, predicts that implementing health policy interventions is not only a technical exercise but a political process limited by the decisions that has been made in the past, even though past circumstances may no longer be relevant (Gomez & Atun, 2013). The theory predicts that implementing HWL policies would be not only a technical exercise requiring drafting a set of regulations, developing and testing warning phrases and images and graphic design (Drope & Ross, 2012) but a path-dependent regulatory process, where earlier decisions on HWL policies impact future choice of options. Despite widespread FCTC ratification there is a large variation in legislation implementing HWLs among low and middle income countries (LMIC), especially in Africa (Tumwine, 2011; H. L. Wipfli, Fujimoto, & Valente, 2010). Using similar strategies as in wealthier countries, the tobacco industry works to block or weaken HWLs among LMICs (Lee, Ling, & Glantz, 2012) (for example Costa Rica (Crosbie & Glantz, 2012), Lebanon (Nakkash & Lee, 2009), Malaysia (Assunta & Chapman, 2004), Philippines (Alechnowicz & Chapman, 2004), and Uzbekistan (Gilmore, Collin, & Townsend, 2007)). The strategies that the tobacco industry has used include submissions to government, privately influencing politicians and the media, using third parties to argue the industry's position, commissioning research (including opinion polls and legal research) arguing that people already know the hazards of smoking, arguing that HWLs conflict with other national laws and international treaties and litigation (Crosbie & Glantz, 2012; Lee et al., 2012). The tobacco industry has delayed also the passage of effective HWLs by making agreements on voluntary HWLs: by 2012 66% of countries with

initial mandated HWLs reached FCTC compliance compared with only 20% of countries with initial voluntary HWLs (Sanders-Jackson et al.).

With regard to the theoretical framework of path-dependency it is noteworthy that in 1992 Philip Morris, followed by other companies, decided to voluntarily place US English language HWLs on all its exported cigarettes to countries that did not have specific national requirements (Hiilamo et al., 2012), which slowed adoption of mandated HWLs (Sanders-Jackson et al.). Wipfli et al. showed that countries that had active participation within global tobacco control networks during the drafting of the FCTC adopted policies that the treaty promoted (Wipfli & Huang, 2011). The result supports the path-dependency theory. The decision to participate in global tobacco control networks created a path-dependency towards FCTC compliance. The passing of the first HWL policy in a LMIC is a contingent event that sets into motion institutional pattern that have deterministic properties (Mahoney, 2000). The evolution of HWL policies can be seen as a set of reactive sequences that are temporally ordered and causally connected events. The chain can be seen as a path leading up to the outcome, in this case the HWL policy in 2013.

This research investigates the effects of FCTC ratification, state capacity, path-dependency and tobacco industry activity on the implementation of FCTC Article 11 compliant HWLs among LMICs. The hypothesis is that FCTC ratification is positively associated with implementation of Article 11 compliant HWLs, while there is a negative association between tobacco industry activity and compliance.

## METHODS

The analysis focuses on the 118 LMICs with populations above 500,000, 105 of which had ratified FCTC as of May 2013. Six countries had signed FCTC but not ratified it, while seven countries had not signed the treaty (see online supplementary table. Because 103 of the 118 LMICs had ratified the treaty by 2010 (Turkmenistan in 2011 and Uzbekistan in 2012, while 15 LMICs had not ratified as of May 2013) the dependent variable is compliance as of May 2013.

Logistic regression was used in two separate analyses, one for FCTC Article 11 compliant HWLs (minimum requirement) and one for GHWLs (gold standard), which were assumed to be FCTC compliant. We obtained data on HWLs among LMICs from the WHO Report on the Global Tobacco Epidemic 2011 (World Health Organization, 2011), a report compiled by Canadian Cancer Society (Canadian Cancer Society, 2012) describing the global HWL policies as of October 2012, and a database developed for our earlier studies (Hiilamo et al., 2012; Sanders-Jackson et al.) (Table 1).

The analysis of FCTC ratification (or accession in legal terms) used the date that the treaty entered into force in each country (generally three months after ratification). We study the effect of FCTC ratification by calculating the number of years since FCTC ratification in 2013. No country in the analysis had FCTC compliant HWLs before ratification.

We use the state fragility index of 2010 developed by Marshall and Cole to quantify state capacity (or, more precisely, incapacity) to implement HWL policies (Marshall & Cole,

2011). This index ranks all countries with population above 500,000 in four performance dimensions: security, political, economic, and social. The most stable countries score 0 (21 countries including two LMICs, Costa Rica and Latvia, in 2010) and the most fragile country scores 25 (Somalia). Fragility is closely associated with a state's capacity to make and implement public policy and their resilience in maintaining system coherence, cohesion, and quality of life.

The World Bank (World Bank, 2013) divides LMICs into three categories based on gross national income (GNI) in 2011: low income economies (GNI \$1,025 or less coded 0), lower middle income economies (GNI \$1,026 - \$4,035, coded 1) and upper middle income economies (GNI \$4,036 - \$12,475, coded 2).

We measure tobacco industry activity by the logarithm (base 10) of the number of previously secret tobacco industry documents in the UCSF Legacy Tobacco Documents Library (<http://legacy.library.ucsf.edu>, searched in February 2013 in which the country's name appeared on documents dated from 1970, when HWLs were first introduced among LMICs (Cuba, Panama and Peru) through February 2013. The Legacy Tobacco Documents Library (LTDL) contains more than 14 million documents created by major tobacco companies related to their advertising, manufacturing, marketing, sales, and scientific research activities covering the period from 1900 to 2013 but with the bulk of documents covering the 1950s through 2009. The names of the countries Chad, Georgia, Guinea, Jordan and Mali generated a large number of documents not related to those countries (e.g., documents about people named Chad or related to guinea pigs). To obtain document counts for these countries we searched for them in the British American Tobacco (BAT) collection, which is a LTDL's sub-collections that includes country name as separate metadata field. For each country mentioned above, we defined a reference country (Benin for Chad, Venezuela for Colombia, Moldova for Georgia, The Gambia for Guinea, Lebanon for Jordan, and Mauritania for Mali). We search BAT documents with country metadata information for all these countries. By comparing the number of reference country's documents from both collections we were able to calculate a ratio. We used this ratio as a multiplier for country's document count in BAT collection to adjust the total number of documents in the entire collection (i.e., for Chad there were 21,156 documents before adjustment and 16,260 after adjustment).

Analyses were carried out with Stata version IC 11.2.

Ethics approval was not required as there were no human subjects involved in this study.

## RESULTS

More than half of the LMIC were in compliance with FCTC as of May 2013 with low income countries having the lowest compliance (Table 2). Of the 62 countries that had implemented FCTC compliant HWLs, 31 had implemented GHWLs, mostly the upper middle income countries. Only two countries from the low income group and eight countries from the lower middle income group had GHWLs.

FCTC ratification was followed by an increase in the odds that LMICs had FCTC compliant HWLs in 2013 (Table 3). The odds of FCTC compliance increased by a factor of 1.31 for each year after FCTC ratification ( $p<0.01$ ) (Table 3).

The more fragile the states were (with higher state fragility scores), the less likely they implemented FCTC compliant HWLs ( $p<0.05$ ). The countries with voluntary HWLs in 1992 were less likely ( $OR= 0.19$ ,  $p<0.01$ ) to comply with FCTC 21 years later (in 2013). In the full model income group was not significantly associated with adopting FCTC compliant HWLs.

In contrast to our hypothesis tobacco industry activity was positively associated with FCTC compliance. For every order of magnitude (log) increase in the number of documents mentioning a country, the odds of FCTC compliance increased by a factor of 3.00 ( $p<0.05$ ). A analysis with another measure of tobacco industry activity,  $\log_{10}$  of the number of tobacco industry documents for each country where key words “warning” or “HWL” appeared in the same documents, produced the same results.

Similar to the results of minimum FCTC Article 11 compliance requirement, the odds of passing GHWLs (gold standard) increased by a factor of 1.47 ( $p<0.05$ ) per year after FCTC entered into force and by a factor of 3.29 ( $p=0.053$ ) for every order of magnitude (log) increase in industry documents (Table 3). State capacity and having voluntary HWLs in 1992 were not significantly related the adoption of GHWLs in 2013. The variance inflation factors did not indicate multicollinearity among the independent variables (mean VIF 1.83, highest value 2.36).

Analysis of the full sample of 132 LMICs without the variable on state fragility (no data on state fragility were available for LMICs with population below 500,000) yielded similar results as Table 3.

## DISCUSSION

The experience of LMIC with HWLs is consistent with the theory of path-dependency on institutional change. In accordance with earlier findings from all countries (Sanders-Jackson et al.; Wipfli et al., 2010) we found that HWL policies among LMIC are path-dependent with respect to voluntary HWLs, meaning earlier decisions on HWL policies affect subsequent policy decisions. Passing a HWL policy is marked by “inertia,” i.e., once the process of agreeing of particular HWLs and printing them on cigarette packs is set into motion, the process tends to stay in motion, reproducing a particular institutional pattern over time. They are difficult to reverse even in the wake of new policy innovations and external pressure (Gomez & Atun, 2013). When new policy instruments to improve public health are legislated it is important for public health advocates to pay attention to the fact that early decisions on policy design establish self-reinforcing patterns that sustain over time. Once an ineffective policy is put into place the path-dependency makes it hard to introduce improvements. The tobacco industry has promoted voluntary agreements with governments as an alternative to tobacco control legislation (Vogel, 2010). LMICs that avoided agreements with the tobacco industry in the early 1990 were more likely to comply

with FCTC regulations in 2013. The fact that state capacity and having voluntary HWLs in 1992 were no longer significantly related to the adoption of GHWLs in 2013 is explained by income group becoming more important for passing GHWLs, with upper middle income countries more likely to enact GHWLs than (OR 2.66,  $p=0.06$ ; Table 3).

These findings not only the importance of long-term commitment to passing laws protecting public health but also the need for vigilance against any industry efforts to circumvent mandatory policies through voluntary arrangements. This concern applies not only industry policies favoring voluntary agreements in tobacco control (Crosbie & Glantz, 2012; Lee et al., 2012) but also in other products with known health risks such as alcohol and junk food. Contrary to the expectation there would be a positive relationship between tobacco industry activity measured by the number of tobacco industry documents and passing of FCTC compliant HWL laws. These results suggest the industry has been focusing particularly on those countries where progressive policies have been proposed and implemented. The fact that industry surveillance and effective HWL outcomes were positively associated demonstrated that tobacco industry's efforts to undermine HWLs can be overcome (Chantornvong, Collin, Dodgson, Lee, McCargo, Seddon et al., 2000).

Our results for LMICs are also consistent with previous findings based on all UN member countries that ratifying FCTC earlier increased the likelihood that countries would enact FCTC compliant HWL laws (Sanders-Jackson et al.). The positive effect of FCTC is, however, countered by the fact that poorest countries are lagging behind lower middle income countries and middle income countries (Table 2). Effective tobacco control policies remain largely unimplemented in most LMICs (Bump & Reich, 2013; El Awa, 2010). These countries also often experience serious difficulties not only in the prevention of tobacco smoking, but in any medical program, including vaccinations, prevention of sexually transmitted infections, prevention of tuberculosis and malaria. In contrast to implementing these medical programs, however, HWLs cost little and do not require substantial infrastructure to implement. Given the demonstrated effectiveness and low cost of HWLs it is disturbing that almost one half of LMICs with population above 500,000 had not implemented FCTC compliant HWLs by 2013 (Table 2). Ten countries out of 56 non-compliant countries had not signed or the ratified the treaty. The rest had ratified but did not comply. The question is why some countries comply while others do not go beyond ratification.

Promoting the FCTC might not be effective as a standalone tobacco control prescription for the most fragile states lacking basic functions of government (Bump & Reich, 2013; Leischow, Ayo-Yusuf, & Backinger, 2012). The adoption of effective tobacco warning labels -- or any other evidence based health policy intervention -- is not an isolated policy failure but part of larger dimension of state capacity and path-dependency. By definition fragile states have difficulties addressing public policies not just tobacco control. There has been a shift in the development aid community from individual project aid to direct budget support aiming to strengthen the capacity of the state (Booth, 2012), which might also improve tobacco control performance as well as other types of public health interventions.



## Limitations

We were unable to study the role of state capacity for those 14 LMICs with population less than 500,000. When we repeated the analysis including all 132 countries but without the state capacity variable the results were similar to those in Table 3. This analysis focused on how much a country is actually putting relevant laws and regulations into effect. We do not have data to describe if HWL policies are actually enforced. Selling cigarettes as sticks, selling tobacco products under the counter (Tumwine, 2011), and selling hand-rolled tobacco such as bidi without any type of HWLs continue in the least developed countries.

## Conclusions

Consistent with the theory of path dependency, the FCTC has promoted HWL policies among LMICs. Adopting voluntary HWL policies in 1992 reduced likelihood of having FCTC compliant HWLs 21 years later. Legislators and other policymakers should not accept industry voluntary agreements in tobacco and be extremely cautious about accepting voluntary agreements in other areas of public health. The stability of the state was also connected with implementation of FCTC compliant HWL policies. The results imply that public health regulations require investment in broader state capacity.

## Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

## Acknowledgments

This work was supported by National Cancer Institute Grant CA-087472. The funding agency played no role in the selection of the research question, conduct of the research, or preparation of the manuscript.

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**HIGHLIGHTS**

- LMICs enacted cigarette warnings after ratifying the Framework Convention on Tobacco Control.
- LMICs with agreements with cigarette companies were less likely to have FCTC-compliant warnings.
- More fragile LMICs remained less likely to implement FCTC compliant HWL policies.
- Results support theory of path-dependency for institutional change in public health

**Table 1**

Variables and data sources in the study.

Variable	Data source
FCTC Article 11 compliancy	WHO Report on the Global Tobacco Epidemic 2011 (World Health Organization, 2011), a report compiled by Canadian Cancer Society (Canadian Cancer Society, 2012), a database developed for two earlier studies (Hiilamo et al., 2012; Sanders-Jackson et al.)
FCTC ratification	WHO, <a href="http://www.who.int/fctc/signatories_parties/en/">http://www.who.int/fctc/signatories_parties/en/</a>
State capacity	State fragility index 2010 (Marshall & Cole, 2011)
Material resources	World Bank 2013 lending categories (World Bank, 2013)
Tobacco industry activity	Tobacco industry documents, <a href="http://legacy.library.ucsf.edu">http://legacy.library.ucsf.edu</a>

**Table 2**

LMICs by income group and FCTC compliance in 2013.

Income group	Compliance with FCTC		Fraction of compliant countries	Number of countries	GHWLs	
	Compliant	Non-compliant			Fraction of countries with GHWLs	
Low income	10	25	29%	2	6%	
Lower middle income	22	20	52%	8	19%	
Upper middle income	30	11	73%	21	51%	
Total	62	56	53%	31	26%	

**Table 3**

Probability of passing FCTC compliant HWLs and GHWLs among LMICs.

	FCTC compliant HWLs		GHWLs	
	Odds ratio	95% CI	Odds ratio	95% CI
Years since FCTC ratification	1.31**	(1.09–1.57)	1.47*	(1.07–2.01)
State capacity	0.86*	(0.76–0.97)	0.98	(0.86–1.11)
Income group (per income group)	0.74	(0.32–1.70)	2.66	(0.96–7.36)
Voluntary HWLs in 1992	0.19**	(0.05–0.65)	0.77	(0.14–4.05)
Mandatory HWLs in 1999	0.69	(0.19–2.45)	2.36	(0.43–13.16)
Tobacco Industry Activity ( $\log_{10}$ number of industry documents)	3.00*	(1.12–9.99)	3.29	(0.98–11.01)
Number of observations	118		118	