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### Short report

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

## Heikki Hiilamo<sup>a</sup>, Stanton A. Glantz<sup>b,\*</sup>

<sup>a</sup> University of Helsinki, Finland

<sup>b</sup> Department of Medicine, Center for Tobacco Control Research & Education, Philip R. Lee Institute for Health Policy Studies, University of California, San Francisco, USA

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#### ABSTRACT

We investigates the effects of ratifying the WHO Framework Convention of Tobacco Control (FTCT), 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 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.

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#### 1. 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 et al., 2012; World Health Organization, 2011) and which started to spread in the early 2000s, are even more effective than text-only warnings (Aftab et al., 1999; Canadian Cancer Society, 2012; Hammond, 2011;

\* Corresponding author. Center for Tobacco Control Research & Education, UCSF, 530 Parnassus Ave., Suite 366, Box 1390, San Francisco, CA 94143-1390, USA. *E-mail address:* glantz@medicine.ucsf.edu (S.A. Glantz). Hammond et al., 2007; Nascimento et al., 2008; Thrasher et al., 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 et al., 2013). 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-ratifiying 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







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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 and 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 and Ross, 2012) but a pathdependent 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 et al., 2010). Using similar strategies as in wealthier countries, the tobacco industry works to block or weaken HWLs among LMICs (Lee et al., 2012) (for example Costa Rica (Crosbie and Glantz, 2012), Lebanon (Nakkash and Lee, 2009), Malaysia (Assunta and Chapman, 2004), Philippines (Alechnowicz and Chapman, 2004), and Uzbekistan (Gilmore et al., 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 and 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., 2013).

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., 2013). 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 and Huang, 2011). The result supports the path-dependency theory. The decision to participate in global tobacco control networks created a pathdependency towards FCTC compliance. The passing of the first HWL policy in an 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.

#### 2. 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 (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., 2013) (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 and 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 (2013) divides LMICs into three categories based on gross national income (GNI) in 2011: low income economies (GNI \$1025 or less coded 0), lower middle income economies (GNI \$1026-\$4,035, coded 1) and upper middle income economies (GNI \$4036-\$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 an 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

Table 1					
Variables and	l 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;
FCTC ratification State capacity	Sanders-Jackson et al., 2013) WHO, http://www.who.int/fctc/signatories_parties/en/ State fragility index 2010 (Marshall and Cole, 2011) World Burk 2013 Janding extensives (World Burk 2013)
Tobacco industry activity	Tobacco industry documents, http://legacy.library.ucsf.edu

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