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EFFECT OF THE FRAMEWORK CONVENTION ON TOBACCO CONTROL AND VOLUNTARY INDUSTRY HEALTH WARNING LABELS ON PASSAGE OF MANDATED CIGARETTE WARNING LABELS 1965 TO 2012: TRANSITION PROBABILITY AND EVENT HISTORY ANALYSES

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Abstract

Objective—This paper quantifies the pattern and rate of passage of HWLs on cigarette packages, including the effect of the WHO Framework Convention on Tobacco Control (FCTC) and HWLs voluntarily implemented by tobacco companies.

Methods—Transition probability matrices were used to describe the pattern of HWL passage and rate of change in four time periods. Event history analysis was used to estimate the effect of the FCTC on adoption and to compare that effect between countries with voluntary HWLs and those with mandatory HWLs.

Results—The number of HWLs passed during each time period accelerated, from a transition rate among countries that changed from 2.42/year in 1965–1977 to 6.71/year in 1977–1984, 8.42/year in 1984–2003, and 22.33/year in 2003–2012. The FCTC significantly accelerated passage of FCTC compliant HWLs for countries with initially mandatory policies with a hazard of 1.27/year

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HUMAN SUBJECTS
No human subjects.

AUTHOR CONTRIBUTIONS
ASJ completed the analyses and wrote the first draft of this manuscript. AVS contributed to the analytical strategy used in this paper. HH contributed the coding system for HWLs. SAG served as senior author and was involved in all levels of the process including initially developing the coding system, contributing intellectually to the analysis and substantially revising the paper. All authors contributed to revising drafts of the current manuscript. SAG serves as the guarantor for the study.

DISCLOSURE
(1) ASJ, AVS, HH and SAG have no other support for the submitted work other than what is described above; (2) ASJ, AVS, and SAG have no relationships with any companies that might have an interest in the submitted work in the previous 3 years; (3) their spouses, partners, or children have no financial relationships that may be relevant to the submitted work; and (4) ASJ, AVS, and SAG have no non-financial interests that may be relevant to the submitted work. HH served without renumeration as an expert witness for a plaintiff in tobacco litigation, Salminen v. Amer Sports Oyj and BAT Finland in 2008 and in 2009. HH's spouse or children have no financial relationships that might be relevant to this work.

(95% CI=1.11–1.45), but only marginally increased the hazard for countries that had an industry voluntary HWL 1.68/year (.95–2.97).

Conclusions—Passage of HWLs is accelerating, with the FCTC being associated with further acceleration of the passage of HWLS. Industry voluntary HWLs slowed mandated HWLs.

Keywords

smoking; public policy; tobacco

INTRODUCTION

The United States implemented the first cigarette package health warning label (HWL) in 1966 with the weak message, “Cigarette smoking may be hazardous to your health” on the side of the pack. By 2012, 209 countries and territories had implemented HWLs, ranging from weak text messages on the side of the pack to strong graphic warning labels (GWLs) on the pack front.[1] Experimental and epidemiological data suggests that HWLs, especially GWLs, are important tools in tobacco control.[2] Indeed, there is some evidence that GWLs enhance relevance and perceived effectiveness of tobacco control messages for individuals in disadvantaged groups[3] and smokers cite GWLs as a impetus for quitting.[4] Fong et al. prepared an extensive review of GWL literature that was published in 2009 concluding that GWLs have been an effective tobacco control intervention in numerous countries worldwide and may reduce disparities in knowledge for tobacco-related harms in countries with low literacy.[5] The World Health Organization Framework Convention on Tobacco Control (FCTC) is a public health treaty design to address issues of tobacco control. Article 11 of the treaty commits parties to implement large (at least 30% of the front surface area of the pack) rotating labels that may include graphics that may disrupt the impact of brand imagery on packaging and decrease the overall attractiveness of the package.[6–7]

By applying transition probability matrices and event history analysis, we quantify the effects of voluntary industry regulation on the underlying process of implementation of HWLs. Understanding how voluntary regulation impedes adoption may help explain why some countries never adopt mandatory HWLs and health policies more generally. Indeed, voluntary regulations have been used to preempt regulation in other health-related areas[8] including food advertising and labeling regulation.[9] This is particularly important in public health as many industries use voluntary regulation to preempt or delay the regulatory process.

There has been some research quantifying the affect of the tobacco industry and the FCTC on smokefree policies. There is some evidence that being connected to GLOBALink (a tobacco control online community) increased the likelihood of ratifying the FCTC.[10] Further, there was a positive effect of the FCTC on strength and presence of tobacco control policies in individual countries.[11] In examining the implementation of HWLs, it is important to consider tobacco companies’ attempts to hamper this process.[1] One way that tobacco companies seek to block or delay tobacco control policies is implementing ineffective voluntary regulation to displace advertising restrictions [12–13], smokefree policies[14], avoid taxation[12, 15] and delay the FCTC itself.[16] HWLs were no different. Between 1992 and 2012, 15 countries made voluntary agreements with the industry to put weak HWLs on cigarette packages and in 1992 Philip Morris unilaterally put English language HWLs on the sides of packages being sold in 49 small, mostly African, countries whose native languages were not English.[1, 17] British American Tobacco followed the same practice soon after. To date, no one has quantified the effect of these voluntary industry HWLs (whether by voluntary agreement or unilateral) on the rate of adoption of stronger HWLs. This paper describes the process of adopting HWLs over time beginning with the first mandated

warning labels in the United States in 1966.This paper also tests whether the FCTC affected adoption of HWLs and quantifies the effect of voluntary industry HWLs on the adoption of strong HWLs.

METHODS

Data

We collected information on HWLs from WHO reports on tobacco epidemic from 2008, 2009 and 2011[7, 18–19], the Canadian Cancer Society *Cigarette Package Health Warnings International Status Report 2012*[20–21] and tobacco industry documents available at the UCSF Legacy Tobacco Documents Library (http://legacy.library.ucsf.edu). Information included the nature and date of implementation of each HWL. We collected data from 1965 (the year before the first HWL in the US) through October 2012. A HWL was considered FCTC compliant if it is rotating and covers at least 30% of the frontal surface

Current UN Member states were analyzed because they represent the vast majority of rule-making entities and clearly have the legal power to mandate HWLs.

Extending previous work on HWLs[1], we scored government mandated HWLs on a 6 level ordinal scale, from vague text HWLs on the side of the cigarette packages (the original US HWL) to strong graphic HWLs on the front of the packages (Table 1). We also identified countries that initially had voluntary industry HWLs (the 16 countries with voluntary agreements between the tobacco industry and government and the 51 countries where tobacco companies unilaterally implemented HWLs). The event history analysis did not allow for backsliding from mandated to voluntary industry HWLs. Therefore, the Philippines, Hungary, Japan, Uganda, Azerbiajan, the Bahamas and Iceland were dropped from the event history analysis because the data from these countries included a transition from a stronger HWL to a weaker HWL or to no HWL.

HWLs were coded by two observers. Inter-coder reliability using an ordinal Krippendorff's α was ·99 (computed using the R concord package kripp.alpha command, updated 25 Mar 2011).

Analyses

Transition probability analysis—This analysis describes the sequence of HWLs and the pace of transition from one type of HWL (including voluntary industry HWL) to the next. We calculated the probability of transitioning to an HWL at the end of the time period based on the country's HWL status at the beginning of the time period. Specifically, we computed the number of countries in which a particular HWL transitioned to a different HWL during each time period, which produced a count for each type of transition. We then converted these counts to transition probabilities by dividing by the total number of transitions that occurred.

To investigate whether the pattern and adoption rate of HWLs has changed over time, we defined four time periods. The first period, 1965 thru 1977, lasted from the time of the first (US) HWL (score 1) to the first rotating detailed health messages on the front of the pack (score 4). The second period, 1977 thru 1984, ended with the first GWL in Iceland. The third period, 1984 thru 2003, ended with the first opportunity to sign the FCTC. (We selected the first opportunity to sign the FCTC, 2003, rather than FCTC ratification, 2005, because the topic of the FCTC itself, including discussions to sign, may have influenced HWL implementation.) The fourth period, 2003 thru 2012, extended through the final year in our sample.

To avoid losing any data, the same year that ended each period was taken as the first year of the subsequent period. Countries with no transition are not included in the transition probability analysis. These countries are reported on the diagonal of Table 2 and discussed separately in the Results.

The Multi-State Markov package (updated 10 Sep 2011) in R was used for the calculation of transition matrices.

Event History Analysis—We used Cox proportional hazard models in three event history analyses to quantify predictors of three HWL events: (1) mandated rotating HWLs that do not occupy 30% of a pack (score 4), (2) FCTC compliant HWLs rotating on the front cover and back and occupy at least 30% of front surface area of a pack (score 5), and GWL (score 6). We stratified the analyses on whether the first HWL was required by law (N=124 countries) or voluntarily instituted through agreement between a government and the tobacco industry or unilaterally by the industry (n=65 countries; as noted above some countries were eliminated from the analysis because they went from mandatory to voluntary HWLs). The independent variables were time (years) since ratification of the FCTC (0 for countries that did not ratify the FCTC), time since first mandated HWL (0 for the absence of a mandated HWL), and strength of first mandated HWL (scored 1–5, see Table 1; 0 for no mandated HWL). As of February 2013, the following WHO members had not ratified the FCTC: Argentina, Cuba, El Salvador, Ethiopia, Haiti, Morocco, Mozambique, Switzerland, and United States. For the 124 countries that began with a mandated HWL, we included 5 categorical variables to represent the 6 WHO regions, with Europe as the reference region. For the 68 countries that began with a voluntary industry HWL, only 18 countries in the strata that started with voluntary industry HWLs implemented FCTC-compliant HWLs and only 7 implemented GWLs. Therefore, the WHO region categorical variables could not be included to avoid having an overspecified model. Countries with no HWL were included in the analysis of 126 countries with mandated HWLs.

The stset commands in Stata IC version 12 were used for the event history analysis.

RESULTS

Patterns of HWL adoption and rates of change over time

The trajectory of HWL passage was almost always from weaker HWL to stronger HWL (Table 2). However, there were a number of exceptions. For example, Iceland, which went from having definite HWL (score 2) in 1969 to no HWL in 1972 and then to a rotating HW (score 4) in 1985. Japan went from having a required HWL to a voluntary HWL and back to a required HWL.

The diagonal elements in Table 2 show countries that did not change HWL status during each of the four time periods. Between 1965 and 1977, only 27 countries adopted HWLs (including 4 that adopted voluntary industry HWL), leaving 164 countries without any HWL. Between 1977 and 1984, the number of countries with no HWL dropped to 129 countries through a combination of countries with HWL moving to stronger HWL and countries introducing new HWL. Over time, the number of countries without an HWL decreased to only 6 by 2012. The rate of transition increased; excluding countries that had already reached FCTC compliant rotating HWL or GWL, 164 countries did not transition from one type of HWL to another in 1965–1977, 152 in 1977–1984, 62 in 1984–2003, and 45 in 2003–2012. (26 of these countries had voluntary industry HWLs.)

Among the countries that changed their HWLs during each period, the number of HWLs passed during each time period accelerated, from a transition-rate of 2.42/year in 1965–1977

to 6.71/year in 1977–1984, 8.42/year in 1984–2003, and 22.33/year in 2003–2012. The median number of steps within HWL transitions remained stable across the four periods (1965–1977: median=1, IQR=1–2; 1977–1984: median=3, IQR=1–3; 1984–2003: median=1, IQR=1–2; 2003–2012: median=2, IQR=1–3). The pattern of change in HWLs varied across time periods. During the first two periods (1965–1977 and 1978–1984) the most common transitions were from an absence of mandated HWLs to messages depicting smoking as a vague health hazard and definite health hazard ("vague HWL" and "definite HWL"). During the third period (1984–2003), most countries without an existing HWL implemented some type of HWL or had a voluntary industry HWL implemented for them. Most HWLs that changed during the third period moved from no HWL to either voluntary industry tobacco industry HWLs ("Vol HWL" in Table 2) or a mandated definite health messages ("definite HWL"). During the final period (2003–2012), most of the new HWLs (170 out of 198) were at least within the category of "definite HWL", though 37 countries kept lower level HWLs or had no HWL.

Effect of FCTC on HWL adoption

Countries that began with mandated HWLs reached FCTC compliance (i.e., both GWLs and rotating HWLs) more rapidly and at higher levels than countries that started with voluntary industry HWLs (Figure 1). By 2012, 82 of 122 countries (66%) with initial mandated HWLs reached FCTC compliance compared to only 13 of the 65 countries (20%) with initial voluntary industry HWLs ($p<.001$ by chi-square).The median year in which countries reached FCTC compliance (median=2009, IQR=2008–2011) was not different for countries that began with a mandated HWL than those that started with a voluntary industry HWL (median=2009, IQR=2008–2012).

Countries that began with a mandated HWL may have been more likely to enact GWLs (but not HWLs that do not have graphics) than countries that started with voluntary industry HWLs (Figure 1b). By 2012, 44 of 122 countries with an initially mandated HWL (35%) had GWL, compared to only 7 (11%) of 65 with an voluntary industry HWL ($p<.001$). Perhaps reflecting the more recent introduction of GWLs, the median years that GWLs were enacted was similar for countries that had an initially mandated HWL (median=2010, IQR=2006–2012) and voluntary industry HWL (median=2008, IQR=2008–2011).

Countries that began with mandated HWLs—For each year since ratification of the FCTC, the hazard ratio for a country being FCTC compliant increased significantly by a factor of 1.27/year (95% CI=1.11–1.45) and for a GWL by a factor of 1.40/year (1.13–1.74) (Table 3). For each year since the adoption of the first mandated HWL, the hazard ratio for FCTC compliance increased significantly by a factor of 1.06/year (1.03–1.08 and for having a GWL by a factor of 1.08/year (1.03–1.13). The stronger the score for a country's initial HWL, the earlier the country reached FCTC compliance with initially mandatory HWLs ($p=.01$).

There was significant geographical variability in the results. Controlling for the other variables, all WHO regions had significantly different (lower) chances of having reached FCTC compliance than the European region ($p\leq.001$) except the Western Pacific region ($p=.133$). There was a suggestion that the Americas were more likely to have passed a GWL ($p=.068$), compared to other regions.

Figure A1 and Table A1 in the online supplemental appendix show the results for rotating warning labels, which are qualitatively similar to the results for FCTC compliant warning labels.

Countries that began with voluntary industry HWLs—There was no significant effect of time since FCTC ratification on FCTC compliance for countries that started with voluntary industry HWLs. Enacting a stronger first mandatory HWL was associated with great FCTC compliance 2.18 ($p \leq .001$) and was passing an initially mandatory HWL later hazard ratio=1.11/year (1.05–1.17). There was also some suggestion that time since FCTC compliance had an effect. The hazard ratio for FCTC compliance increased by a factor of 1.68 each year since ratifying the FCTC ($p=.07$).

DISCUSSION

As seen in other tobacco control activities[12–13], tobacco industry delayed the passage of HWLs as few countries that started with industry-volunteered policies reached FCTC compliance. Countries that started with industry voluntary HWLs were slower to progress to FCTC compliant HWLs, and this progress was not related to signing the FCTC, which differed from countries that started with mandated HWLs. The number of countries with voluntary HWLs varied by region and most countries with voluntary HWLs were in Africa (Table 4). In Africa, this pattern may reflect a lack of state capacity, resources, and tobacco industry interference.[22] Voluntary HWLs pulled the median number of transitions down during later periods since very few countries that began with voluntary HWLs advanced to higher levels.

The FCTC had a positive effect on passage of stronger HWLs and GWLs and the passage of HWLs generally. The rate of HWL enactment increased over time with the initial legally required HWLs becoming stronger, though the incremental improvement between different HWLs (measured as the number of steps between HWLs scores) remained stable. Among countries that began with mandated HWLs, FCTC signatories were more likely to pass FCTC-compliant rotating HWLs (score 5) and GWLs (score 6). Among these countries, the stronger the first mandated HWL, the more likely the countries were to reach FCTC compliance.

The significant effect of time since signing the FCTC on the hazard model statistic of countries that initially had mandatory HWLs likely reflects the social and political process that led to ratification of the FCTC. Countries, non-governmental organizations, and other entities came together to develop the FCTC for years of debate and consensus building.[23–24] The process that led up to the ratification of the FCTC likely affected the passage of HWLs, which was, in turn, augmented by signing and ratifying the FCTC.

Data were analyzed from more than 40 years of tobacco industry and other documents related to cigarette pack HWLs after an extensive search of multiple sources of information. However, it is always possible that some data is missing from the analysis. Further, the Philippines, Hungary, Japan, Uganda, Azerbiajan, the Bahamas and Iceland were dropped from the primary event history analysis because the data from these countries included a transition from a stronger HWL to a weaker HWL, a voluntary HWL or no HWL. A sensitivity analysis using the most recent versions of the HWL for these countries did not substantially change the conclusions of the event history analysis. Sixteen non-UN countries and other entities (e.g., Hong Kong, Taiwan) were not included in either analysis; results from an event history analysis (not presented), including these entities were virtually identical to the event history analysis.

Future research might investigate why HWLs transitions were limited to two categories within each period, specifically focusing on political and social processes that limit the scope of transitions. In this regard, comparisons to implementation of other health-related policies (e.g., smokefree laws) could yield important information on how tobacco control

activities might diffuse and how that process can be improved. Indeed, the food industry has recently implemented voluntary nutritional labels in an effort to prevent several governments and international health organizations from developing and mandating standard nutrition labeling.[25–26] In addition, future analyses might consider building on our current findings by incorporating sociological factors including baseline and change in country-level GDP, type of and change in governmental structure and other related policies that may be in existence in each country

These results illuminate an important relationship between international treaties and processes that affect non-communicable disease burden. The delaying effect of voluntary HWLs on the implementation of mandated HWLs may serve as a warning for other non-communicable diseases. In particular, there are major financial interests that would benefit from halting health-related interventions for other areas, such as food industry activities that affect the obesity epidemic. Policymakers should avoid accepting voluntary agreements with tobacco companies as an alternative to mandated tobacco control policies.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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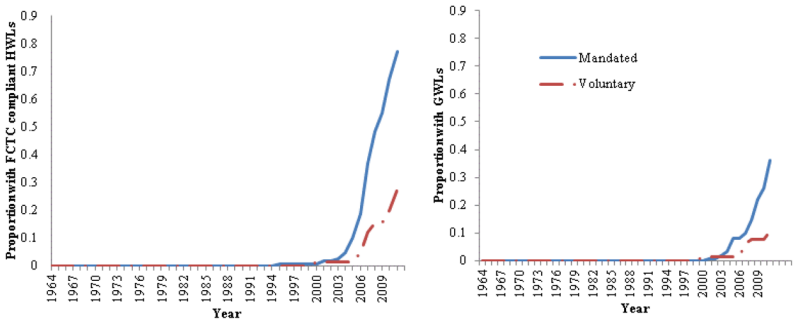

Figure 1.

(Left) Kaplan-Meyer event curve for achieving HWLs that met minimum FCTC requirements (rotating detailed HWLs that covered at least 30% of the pack [Category 5] or GWLs [Category 6]) shows that countries with mandatory HWLs did not achieve FCTC compliant warning labels in the same median year, 2009, as countries with voluntary HWLs. (Right) Kaplan-Meyer event curve for achieving GWLs (Category 6) shows that countries with initially mandatory HWLs achieved GWLs a median of 2 year before countries that started with voluntary self-regulated HWLs.

Table 1

Ordinal scale for HWLs[1]

HWL score (Year of first usage)	HWL description	First implemented example (Country, year)
1: Vague HWL (1966)	Government requirement and vague warning health message on the side of the pack	"Caution: cigarette smoking may be hazardous to your health" (United States, 1966)
2: Definite HWL (1969)	Smoking established as a definite health hazard or specific diseases mentioned, message on the side of the pack	"Warning: Cigarette smoking can cause lung cancer and heart diseases" (on cellophane) (Iceland, 1969–1971)
3: Front HWL (1987)	Affirmative health message on the front of the pack and or on the back of the pack	"Smoking is a main cause of cancer, diseases of the lung, and diseases of the heart and the arteries". (Saudi Arabia 1987)
4: Rotating HWL (1977)	Rotating detailed health messages on the front of pack	"Smokers run an increased risk of heart attacks and certain diseases of the arteries. National Board of Health and Welfare" (one of 16 HWLs) (Sweden, 1977)
5: FCTC compliant HWLs (1996)	Rotating detailed health messages on the front and back of pack covering at 30% of the pack (Minimum FCTC requirement)[1]	Front or back:"Attention! The link between smoking and lung diseases has been scientifically proven. Minister of Health and Social Welfare." Front or back: "Smoking or health - The choice is yours. Minister of Health and Social Welfare." (two of 4 HWLs) (Poland, 1996)
6: GWL (1985)	Graphic Health Warnings, pictures to re-enforce the health message on front and or back of the pack	Eight cartoon Graphic HWLs with images such as a pair of black lungs, a patient in bed or a diseased heart (Iceland, 1985–1996)

We used WHO reports from 2008, 2009 and 2011[7, 18–19] to confirm both FCTC compliant and GWLs and the Canadian Cancer Society Cigarette Package Health Warnings International Status Report 2012[2] to confirm GWLs. With regard to FCTC compliancy we paid attention to both size and rotation of HWLs. FCTC implementation reports[21] were used to fill in some data points between 2003 and 2007 on FCTC compliance. We assumed that no major changes took place in HWL policies between 1999 (our last data point in the tobacco industry documents) and the times reported in the FCTC implementation reports. We assumed that all countries with GWL were FCTC compliant.

Table 2

Probability of change from one category of HWL to another among countries that changed HWL[a]

	HWL following change							
	1965–1977 (Average number of changes/year = 2.42)							
	No HWL	**Vol HWL**	**Vague HWL**	**Definite HWL**	**Front HWL**	**Rotating HWL**	**FCTC HWL**	**GWL**
HWL preceding change								
No HWL	*(164)*	4(.14)	10(.34)	12(.41)	0	1(.03)	0	0
Vol HWL	0	(*0*)	0	0	0	0	0	0
Vague HWL	0	0	(*0*)	1(.03)	0	0	0	0
Definite HWL	1(.03)	0	0	(*0*)	0	0	0	0
Front HWL	0	0	0	0	(*0*)	0	0	0
Rotating HWL	0	0	0	0	0	(*0*)	0	0
FCTC HWL	0	0	0	0	0	0	(*0*)	0
GWL	0	0	0	0	0	0	0	(*0*)
	1977–1984 (Average number of changes/year = 6.71)							
	No HWL	**Vol HWL**	**Vague HWL**	**Definite HWL**	**Front HWL**	**Rotating HWL**	**FCTC HWL**	**GWL**
HWL preceding change								
No HWL	*(129)*	3(.06)	14(.30)	0	20(.43)	1(.02)	0	0
Vol HWL	0	*(3)*	0	1(.02)	0	1(.02)	0	0
Vague HWL	0	0	*(7)*	6(.13)	0	0	0	0
Definite HWL	0	1(.02)	0	*(12)*	0	0	0	0
Front HWL	0	0	0	0	*(0)*	0	0	0
Rotating HWL	0	0	0	0	0	*(1)*	0	0
FCTC HWL	0	0	0	0	0	0	*(0)*	0
GWL	0	0	0	0	0	0	0	*(0)*
	1984–2003 (Average number of changes/year = 8.42)							
	No HWL	**Vol HWL**	**Vague HWL**	**Definite HWL**	**Front HWL**	**Rotating HWL**	**FCTC HWL**	**GWL**
HWL preceding change								
No HWL	*(28)*	60(.38)	16(.10)	22(.14)	1(.01)	5(.03)	0	1(.01)
Vol HWL	0	*(5)*	4(.03)	2(.01)	1(.01)	2(.01)	0	0

	1984–2003 (Average number of changes/year = 8.42)							
	No HWL	**Vol HWL**	**Vague HWL**	**Definite HWL**	**Front HWL**	**Rotating HWL**	**FCTC HWL**	**GWL**
Vague HWL	1(.01)	1(.01)	*(1)*	13(.08)	0	7(.04)	0	0
Definite HWL	2(.01)	2(.01)	0	*(23)*	3(.02)	12(.08)	1(.01)	0
Front HWL	0	0	0	0	*(3)*	1(.01)	0	0
Rotating HWL	0	0	0	0	0	*(2)*	0	2(.01)
FCTC HWL	0	0	0	0	0	0	(0)	0
GWL	0	0	0	0	0	1(.01)	0	(0)

	2003–2012 (Average number of changes/year = 22.33)							
	No HWL	**Vol HWL**	**Vague HWL**	**Definite HWL**	**Front HWL**	**Rotating HWL**	**FCTC HWL**	**GWL**
HWL preceding change: No HWL	*(6)*	0	5(.03)	2(.01)	1(.01)	2(.01)	10(.05)	2(.01)
Vol HWL	0	*(26)*	13(.07)	6(.03)	5(.03)	1(.01)	6(.03)	0
Vague HWL	0	0	*(5)*	2(.01)	4(.02)	1(.00)	6(.03)	2(.01)
Definite HWL	0	0	0	*(6)*	21(.11)	6(.03)	15(.08)	14(.07)
Front HWL	0	0	0	0	*(0)*	5(.03)	14(.07)	7(.04)
Rotating HWL	1(.01)	0	0	0	0	*(0)*	28(.14)	8(.04)
FCTC HWL	0	0	0	0	0	0	*(2)*	13(.07)
GWL	0	0	0	0	0	0	0	*(0)*

[a]Numbers in parenthesis are the number of countries that made each transition. From Table 1: “Vague HWL”=score 1, “Definite HWL”=score 2, “Front HWL”=score 3, “Rotating HWL”=score 4, “FCTC compliant HWL”=score 5 and “GWL”=score 6.

Table 3

Cox proportional hazards model for FCTC compliance and GWLs

	FCTC compliance			GWL		
Predictors	**Hazard Ratio**	**95% CI**	**p**	**Hazard Ratio**	**95% CI**	**p**
Countries initially with mandated HWL (N=122)						
Time since FCTC	1.27	[1.11, 1.45]	≤.001	1.40	[1.13, 1.74]	.002
Time since first HWL	1.06	[1.03, 1.08]	≤.001	1.08	[1.03, 1.13]	.001
Initial HWL score	1.25	[1.05, 1.49]	.014	1.35	[.93, 1.97]	.117
WHO region (Reference Europe)						
Americas	.31	[.16, .61]	≤.001	2.31	[.94, 5.65]	.068
Southeast Asia	.18	[.06, .51]	≤.001	.92	[.20, 4.18]	.917
Africa	.14	[.05, .38]	≤.001	.33	[.04, 2.63]	.298
E. Mediterranean	.17	[.08, .36]	≤.001	1.76	[.74, 4.18]	.203
W. Pacific	.60	[.31, 1.17]	.133	1.98	[.66, 5.88]	.221
Countries with industry self-regulatory HWLs (N=65)						
Time since FCTC	1.68	[.95, 2.97]	.073			
Time since first HWL	1.11	[1.05, 1.17]	≤.001			
Initial HWL score	2.18	[1.56, 3.06]	≤.001			

Time since FCTC is the time that has passed since a country ratified the FCTC. Time is measured in years passed its first mandated HWL. Initial HWL score is for the first mandated HWL (Table 1) a country passed.

Table 4

Number of countries with voluntary HWLs by WHO region

WHO Region	Countries
European	5
Americas	16
Southeast Asia	2
African	33
E. Mediterranean	6
W. Pacific	7