



International Tobacco Control
Policy Evaluation Project

Evaluating the Impact of FCTC Policies: Findings from the FCTC Impact Assessment and the ITC Project

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University of Waterloo**

Senior Investigator, Ontario Institute for Cancer Research



**FCTC Knowledge Hub on Surveillance
Monitoring of Tobacco Control Policies
Webinar – November 9, 2018**



Framework Convention on Tobacco Control (FCTC)

- ◆ Legally binding international treaty: first under the WHO
- ◆ Came into force in Feb 2005; ratified by 180 countries
- ◆ Multisectoral: whole-of-government approach
- ◆ Includes broad range of tobacco control policies:
 - Pictorial warnings
 - Comprehensive smoke-free laws
 - Higher taxes to reduce demand
 - Bans/restrictions on marketing
 - Support for cessation
 - Measures to reduce illicit trade
 - Tobacco product regulation
- ◆ Tobacco industry must be prevented from influencing policies and measures
- ◆ **Greatest disease prevention initiative in history.**





Has the FCTC had an impact?

Impact Assessment of the WHO FCTC



FCTC
WHO FRAMEWORK CONVENTION
ON TOBACCO CONTROL

Conference of the Parties to the
WHO Framework Convention
on Tobacco Control

Seventh session
Delhi, India, 7–12 November 2016
Provisional agenda item 5.2

FCTC/COP/7/6
27 July 2016

Impact assessment of the WHO FCTC:

Report by the Expert Group



- (1) that an impact assessment of the WHO FCTC will be conducted, under the guidance of the Bureau, and as outlined under option A in paragraph 27 of document FCTC/COP/6/15;
- (2) that the purpose of the impact assessment should be to assess and examine the impact of the WHO FCTC on implementation of tobacco control measures **and on the effectiveness of its implementation** in order to assess the impact of the Convention as a tool for reducing tobacco consumption and prevalence after its first 10 years of operation;

- ◆ Chair: Professor Pekka Puska
- ◆ Global evidence review of 17 FCTC articles (ITC Project)
- ◆ Country missions to 12 FCTC Parties
- ◆ Other external reports
- ◆ Report presented at COP7 (Nov 2016; Delhi)

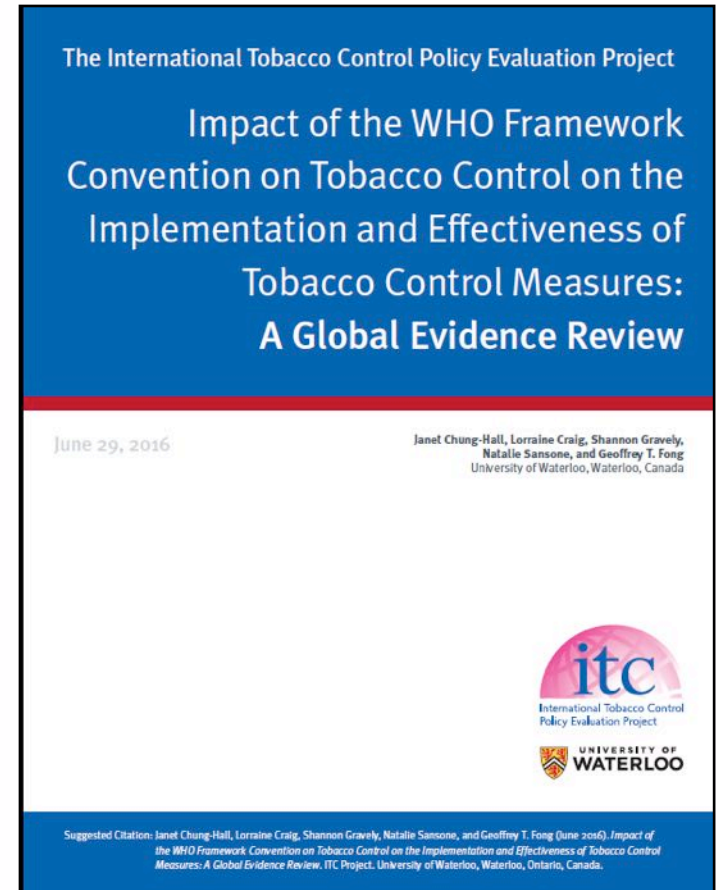
ITC Project Global Evidence Review

ITC Project:

- Janet Chung-Hall, Lorraine Craig, Shannon Gravely, Natalie Sansone, Geoffrey T. Fong, ITC Waterloo

External Reviewers:

- Rob Cunningham, Canadian Cancer Society
- Jeffrey Drope, American Cancer Society
- Gary J. Fooks, Aston University
- Anita George, McCabe Centre for Law and Cancer
- Anna B. Gilmore, University of Bath
- Patricia Lambert, International Legal Consortium, Campaign for Tobacco-Free Kids
- Natacha Lecours, International Development Research Centre
- Jonathan Liberman, McCabe Centre for Law and Cancer
- Monique E. Muggli, International Legal Consortium, Campaign for Tobacco-Free Kids
- Richard J. O'Connor, Roswell Park Cancer Institute
- Martin Raw, International Centre for Tobacco Cessation and University of Nottingham



Impact Assessment Supplement in *Tobacco Control*

Impact assessment of WHO's Framework Convention on Tobacco Control: introduction, general findings and discussion

Pekka Puska,¹ Mike Daube,² WHO FCTC Impact Assessment Expert Group

Impact of the WHO FCTC over the first decade: a global evidence review prepared for the Impact Assessment Expert Group

Janet Chung-Hall,¹ Lorraine Craig,¹ Shannon Gravely,¹ Natalie Sansone,¹ Geoffrey T Fong^{1,2,3}

Impact assessment of the WHO FCTC over its first decade: methodology of the expert group

Geoffrey T Fong,^{1,2,3} Janet Chung-Hall,¹ Lorraine Craig,¹ for the WHO FCTC Impact Assessment Expert Group

Impact of the WHO FCTC on non-cigarette tobacco products

Ghazi S Zaatari, Asma Bazzi

WHO FCTC and global governance: effects and implications for future global public health instruments

Thomas F McInerney

The impact of the WHO Framework Convention on Tobacco Control in defending legal challenges to tobacco control measures

Suzanne Y Zhou,¹ Jonathan D Liberman,¹ Evita Ricafort²

Analysis of Article 6 (tax and price measures to reduce the demand for tobacco products) of the WHO's Framework Convention on Tobacco Control

Corne van Walbeek,^{1,2} Samantha Filby²

Implementation of key demand-reduction measures of the WHO Framework Convention on Tobacco Control and change in smoking prevalence in 126 countries: an association study

Shannon Gravely, Gary A Giovino, Lorraine Craig, Alison Commar, Edouard Tursan D'Espaignet, Kerstin Schotte, Geoffrey T Fong

Gravely et al.:
Published March 2017
in *Lancet Public Health*

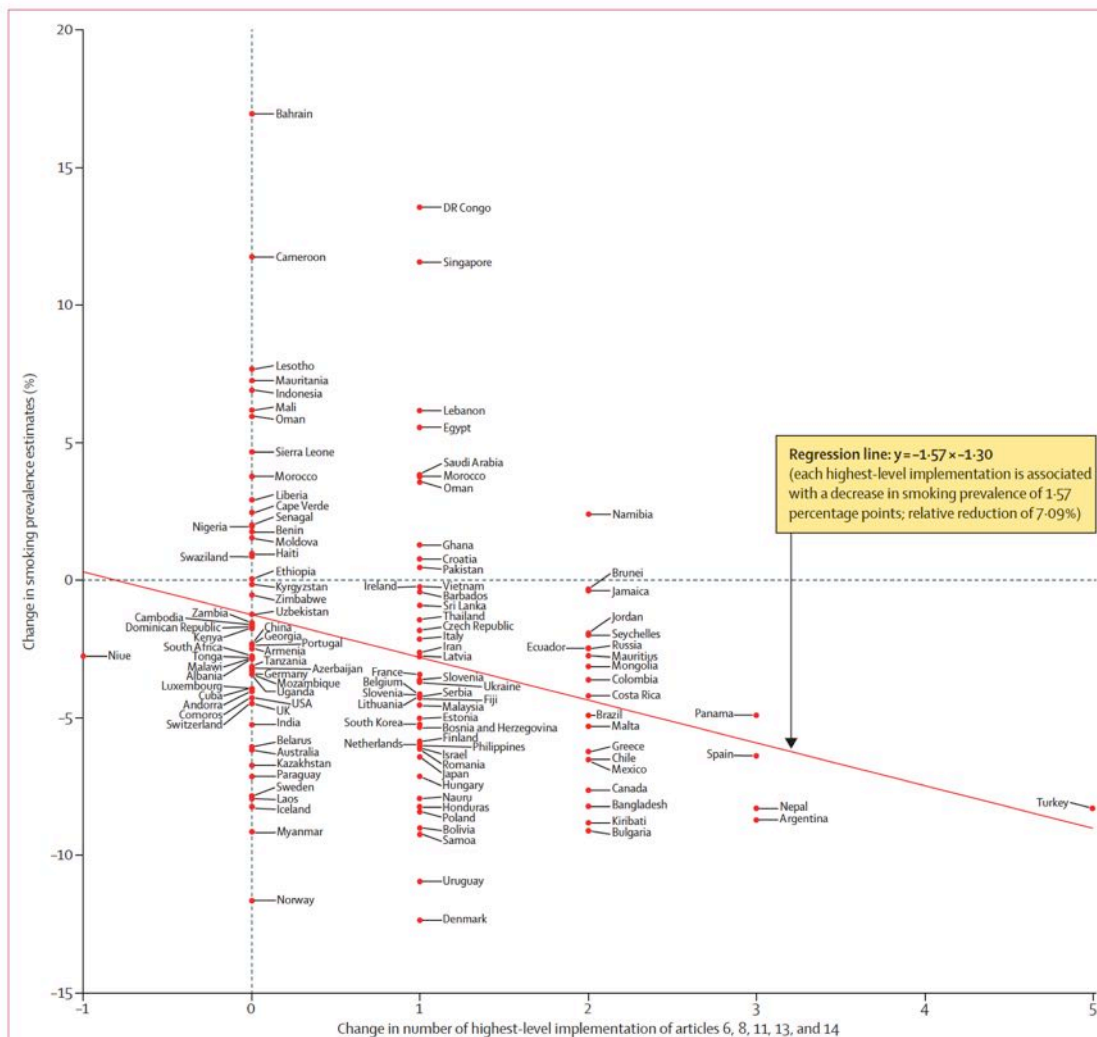


Figure 2: Relation between change in the number of five key WHO FCTC demand-reduction measures implemented at the highest level between 2007 and 2014 (x-axis) and change in smoking prevalence between 2005 and 2015 (y-axis)

- Analysis of WHO data from 126 countries
- **Predictor:** number of highest-level implementations of key demand-reduction FCTC policies between 2007 and 2014
- **Outcome:** WHO smoking prevalence trend estimates from 2005 to 2015 (first decade of the WHO FCTC)
- **Results:** Each additional highest-level implementation associated with 1.57 percentage point decrease in smoking rate (7.09% relative decrease)

The WHO FCTC works...
...if implemented at the
highest level

FCTC and Global Reduction of Smokers

Two Key Questions:

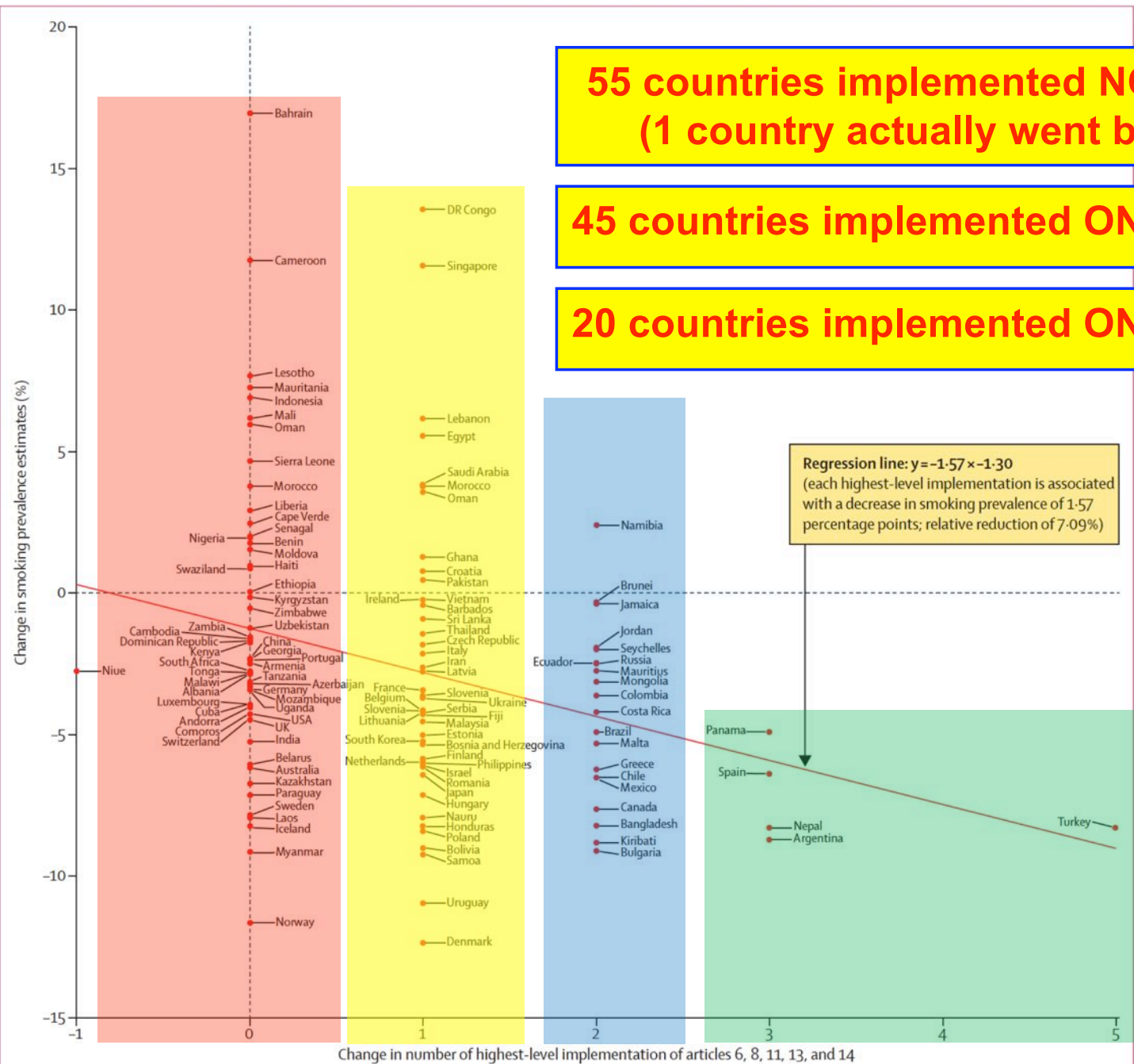
1. How much did implementation of the 5 key demand-reduction FCTC policies reduce the number of smokers in the FCTC's first decade?
2. And how much COULD have been achieved by strong implementation of these 5 policies?

WHO Region	Number of countries TOTAL	Number of Countries with data	(G) Smoking Prevalence in 2005	(H) Number of Smokers in 2005	(S) Smoking Prevalence in 2015	(T) Number of Smokers in 2015	(Z) Average number of FCTC policies implemented as of 2014	(AA) Average number of FCTC policies implemented 2007-14	(AB) Reduction of smokers in 2015 due to FCTC implementation during 2007-14	Percentage reduction achieved by FCTC implementation during 2007-14
African	46	27	11.7	33,530,500	11.8	45,059,674	0.500	0.370	239,280	0.53%
American	34	19	21.3	126,754,699	16.5	113,915,520	1.842	1.474	13,935,630	12.23%
Eastern Mediterranean	22	9	18.8	45,843,176	20.6	63,870,884	1.111	0.667	2,935,836	4.60%
European	53	45	31.6	221,573,786	26.8	195,726,817	1.045	0.909	23,389,252	11.95%
South East Asian	11	8	20.4	231,976,236	16.4	224,981,887	1.000	1.000	5,797,555	2.58%
Western Pacific	27	18	28.3	385,183,712	25.4	377,517,020	1.056	0.722	2,953,913	0.78%
WORLD	193	126	24.2	1,044,862,108	19.0	1,021,071,802	1.040	0.832	49,251,465	4.82%

First decade of the FCTC: highest-level implementation was associated with:

- **World: 49M fewer smokers (4.82% reduction)**
- **EUR: 23M fewer smokers (11.95% reduction)**
- **WPR: 3.0M fewer smokers (0.78% reduction)**

But on average, a country implemented only 1.04 out of the 5 key policies



**55 countries implemented NONE of the 5 policies
(1 country actually went backward, score = -1)**

45 countries implemented ONLY 1 of the 5 policies

20 countries implemented ONLY 2 of the 5 policies

**Very poor
Implementation
of the FCTC**

Figure 2: Relation between change in the number of five key WHO FCTC demand-reduction measures implemented at the highest level between 2007 and 2014 (x-axis) and change in smoking prevalence between 2005 and 2015 (y-axis)

WHO Region	Number of countries TOTAL	Number of Countries with data	(G) Smoking Prevalence in 2005	(H) Number of Smokers in 2005	(S) Smoking Prevalence in 2015	(T) Number of Smokers in 2015	Additional reduction of smokers that COULD have been achieved if countries had implemented all 5 key FCTC demand-reduction policies by 2014	Percentage reduction that COULD have been achieved
African	46	27	11.7	33,530,500	11.8	45,059,674	11,408,938	25.32%
American	34	19	21.3	126,754,699	16.5	113,915,520	26,430,049	23.20%
Eastern Mediterranean	22	9	18.8	45,843,176	20.6	63,870,884	11,800,955	18.48%
European	53	45	31.6	221,573,786	26.8	195,726,817	55,158,655	28.18%
South East Asian	11	8	20.4	231,976,236	16.4	224,981,887	76,438,021	33.98%
Western Pacific	27	18	28.3	385,183,712	25.4	377,517,020	133,593,712	35.39%
WORLD	193	126	24.2	1,044,862,108	19.0	1,021,071,802	314,830,330	30.83%

If all countries had implemented **all five** key FCTC demand-reduction policies, then tremendous **additional** reduction in smokers COULD have been achieved:

- **World: 315M fewer smokers (31% reduction)**
- **EUR: 55M fewer smokers (28% reduction)**
- **WPR: 134M fewer smokers (35% reduction)**

Stronger and more accelerated FCTC implementation can lead to tremendous gains in global health

**In the second decade of the FCTC:
Need to **strengthen** and **accelerate**
implementation of the treaty.**

COP8: Pivoting toward implementation



◆ **Global Strategy to Accelerate Tobacco Control:**

- First-ever strategic plan for the FCTC
- Linked to the broader target of reducing global tobacco prevalence by 30% by 2025
- Potential for fund-raising, enhance international cooperation

◆ **Implementation Review Mechanism:**

- Review of implementation reports submitted by Parties to the Secretariat every 2 years



*“The FCTC is an **evidence-based** treaty that reaffirms the right of all people to the highest standard of health.”*

– FCTC Foreword



“Evidence”
mentioned 5 times

“Scientific”
mentioned 13 times

“Effective(ness)”
mentioned 28 times

What evidence-gathering systems are in place to move the FCTC and tobacco control forward?

- ◆ **Treaty monitoring:** what are the parties doing in their implementation obligations?
 - Two-year and five-year implementation reports
 - WHO: Global Tobacco Control Report
 - Other monitoring efforts by Civil Society
- ◆ **Surveillance:** what is the prevalence of tobacco use and of key tobacco-relevant behaviours?
 - Global Adult Tobacco Survey (GATS) in 16 LMICs + additional countries planned in Africa + 2nd round in some
 - National surveillance systems

Tobacco Epidemic Evidence Systems

FCTC Ratification	<div data-bbox="327 342 1661 391" data-label="Image"> </div> <div data-bbox="373 435 711 537" data-label="Text"> <p>FCTC Policy Implementation</p> </div>		<div data-bbox="1325 435 1570 532" data-label="Text"> <p>Tobacco Prevalence</p> </div>	Tobacco-Related Morbidity and Mortality
Systems	<div data-bbox="352 639 737 737" data-label="Text"> <p>Policy Monitoring Systems</p> </div> <div data-bbox="359 792 730 889" data-label="Text"> <p>FCTC Reports, GTCR, Civil Society</p> </div>		<div data-bbox="1310 639 1585 737" data-label="Text"> <p>Surveillance Systems</p> </div> <div data-bbox="1289 792 1606 889" data-label="Text"> <p>GATS, STEPS, country systems</p> </div>	
Central Question	<div data-bbox="359 954 730 1052" data-label="Text"> <p>What policies have been implemented?</p> </div>		<div data-bbox="1289 954 1606 1052" data-label="Text"> <p>What is tobacco prevalence?</p> </div>	
Evidence Source	<div data-bbox="373 1117 716 1214" data-label="Text"> <p>Legislation, reports from stakeholders</p> </div>		<div data-bbox="1276 1117 1619 1214" data-label="Text"> <p>Individuals from the population</p> </div>	
Measures & analysis	<div data-bbox="352 1279 737 1377" data-label="Text"> <p>Legislative analysis of strength/weakness</p> </div>		<div data-bbox="1262 1279 1633 1377" data-label="Text"> <p>Measures of tobacco use, SHS exposure</p> </div>	

The Path from Laws to Impact

**Law is
passed**



**Regulations
are created**



**Law is
implemented,
communicated,
enforced**



**How
EFFECTIVE
is the law?**

Example: Smoke-free law in India

- ◆ Section 4 of COTPA (India's tobacco control law) prohibits smoking in the inside areas of all public places, including hospitality venues (e.g., restaurants and bars). This law came into force on Oct 2, 2008. **Strong legislation on paper.**
- ◆ ITC Project in India (TCP India Project): Wave 1 (2010-11), 2-3 years after the start date of the national smoke-free law
 1. Very high levels of smoking found in restaurants & bars
 2. Smokers' awareness of the law:
 - Madhya Pradesh: only 18% were aware
 - Maharashtra: only 35% were aware

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Important questions that are not (well) addressed by monitoring and surveillance systems

- ◆ What is the effectiveness of current FCTC policies?
- ◆ When new policies are introduced, are they more effective?
- ◆ What are the ingredients of effective policies? WHY and HOW do policies have their impact? What are the mediating and moderating factors?
- ◆ Are there negative consequences of otherwise effective policies?
- ◆ What is the **relative effect size** of policies (across policies and within a policy)? And does this vary across countries?
- ◆ Does policy effectiveness vary by country income level (e.g., are pictorial warnings as effective in LMICs as they are in HICs?). Does policy effectiveness vary by income level/SES **within a country**? (can policies help to reduce health disparities?)

A rigorous evaluation system can answer these questions and can provide evidence-based guidance for effective policy-making.

Tobacco Epidemic Evidence Systems

FCTC Ratification				Tobacco-Related Morbidity and Mortality
	FCTC Policy Implementation	FCTC Policy Impact	Tobacco Prevalence	
Systems	Policy Monitoring Systems FCTC Reports, GTCR, Civil Society	Impact Evaluation Systems ITC Project	Surveillance Systems GATS, STEPS, country systems	
Central Question	What policies have been implemented?	What is the impact of the policies?	What is tobacco prevalence?	
Evidence Source	Legislation, reports from stakeholders	Individuals from the population	Individuals from the population	
Measures & analysis	Legislative analysis of strength/weakness	Measures of tobacco use, SHS exposure, policy-relevant measures of impact, mediators of behavior	Measures of tobacco use, SHS exposure	

What do we need for evaluation of the FCTC at the level of countries?

- ◆ An international system for measuring policy-relevant variables and important outcome variables over time
- ◆ Common measures selected from a strong, theory-driven perspective
- ◆ Common research designs and protocols
- ◆ Strategic selection of countries to evaluate policy via natural experiments

The International Tobacco Control Policy Evaluation Project (the ITC Project)



Canada



United States



Australia



United Kingdom



Greece



Ireland



Thailand



Malaysia



South Korea



Hungary



China



Uruguay



Mexico



New Zealand



Poland



France



Germany



Netherlands



Bangladesh



Romania



Brazil



Mauritius



Bhutan



India



Spain



Zambia



Kenya



Abu Dhabi



Japan



Mission of the ITC Project

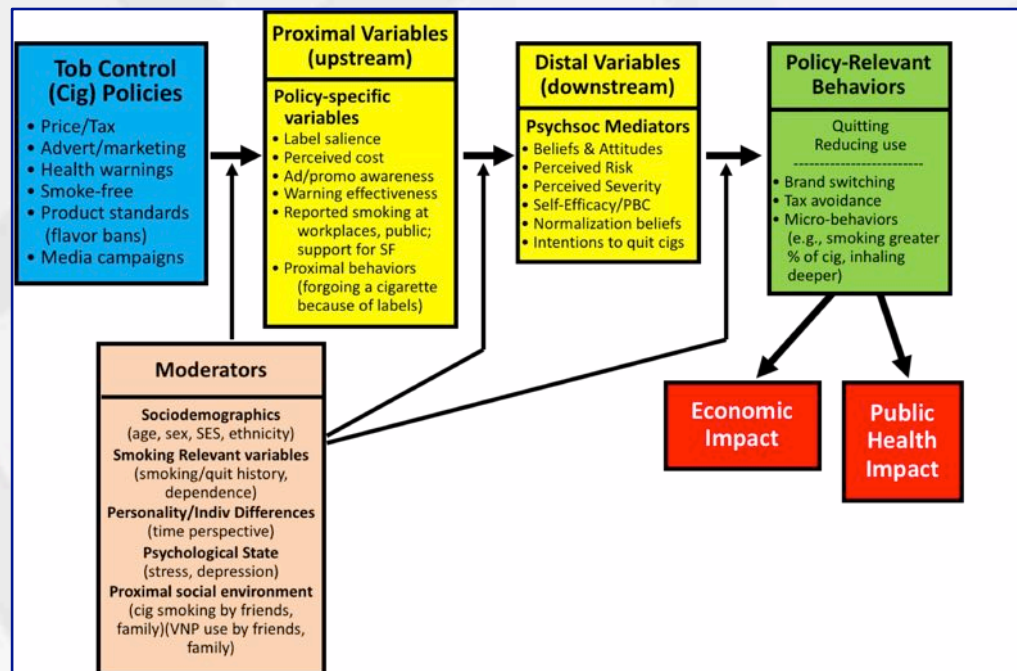
To conduct high-quality research and disseminate findings to strengthen evidence-based approaches to reducing tobacco use throughout the world

Objectives of the ITC Project

- ◆ To conduct rigorous evaluation studies to measure effectiveness and impact of FCTC policies.
 - Are pictorial warnings more effective than text-only?
 - Do higher cigarette taxes lead to lower smoking rates?
 - What kind of enforcement policies are necessary for smoke-free laws to work? Are smoke-free laws accepted by smokers?
- ◆ To compare the impact of FCTC policies across countries
- ◆ To communicate ITC findings to policymakers, governments, advocates, and other stakeholders to support stronger and swifter implementation of evidence-based policies
- ◆ To build capacity for tobacco control research, especially in low- and middle-income countries (LMICs)

Methods of the ITC Project

- ◆ First and still the only multi-country longitudinal cohort study of tobacco use. Key objective: evaluate FCTC policies.
- ◆ 29 countries covering over half of the world's population and over two-thirds of the world's tobacco users.
- ◆ National samples in most countries; probability sampling allowing for generalizations to national level in 20+ countries
- ◆ Conceptual Model specifies pathways from policies to behavior through policy-specific and psychosocial mediators.



ITC Project

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graph TD; ITC[ITC Project] --> ITC_Exp[ITC Experimental Studies]; ITC --> ITC_Surveys[ITC Surveys]; ITC --> ITC_Tobacco[ITC Tobacco Product Project];
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ITC Experimental Studies

Experimental studies on the impact of specific features of health warnings

7 countries: Mexico, US, China, India, Germany, South Korea, Bangladesh

ITC Surveys

Longitudinal cohort surveys of tobacco users (smokers, smokeless users) and non-smokers to measure impact of tobacco control policies, regulations, and other interventions

Being conducted in 29 countries

ITC Tobacco Product Project

Collecting and analyzing leading cigarette brands in 20 countries (linked to ITC Surveys) to assess and evaluate physical characteristics of tobacco products and to understand the relation between design and consumer perceptions, smoking topography, impact on biomarkers of exposure

Research Article

Cancer
Epidemiology,
Biomarkers
& Prevention

Effect of Differing Levels of Tobacco-Specific Nitrosamines in Cigarette Smoke on the Levels of Biomarkers in Smokers

David L. Ashley¹, Richard J. O'Connor², John T. Bernert¹, Clifford H. Watson¹, Gregory M. Polzin¹, Ram B. Jain¹, David Hammond⁴, Dorothy K. Hatsukami⁶, Gary A. Giovino³, K. Michael Cummings², Ann McNeill⁷, Lion Shahab⁸, Bill King⁹, Geoffrey T. Fong^{5,10}, Liqin Zhang¹, Yang Xia¹, Xizheng Yan¹, and Joan M. McCraw¹

Abstract

Background: Smokers are exposed to significant doses of carcinogens, including tobacco-specific nitrosamines (TSNA). Previous studies have shown significant global differences in the levels of TSNA in cigarette smoke because of the variation in tobacco blending and curing practices around the world.

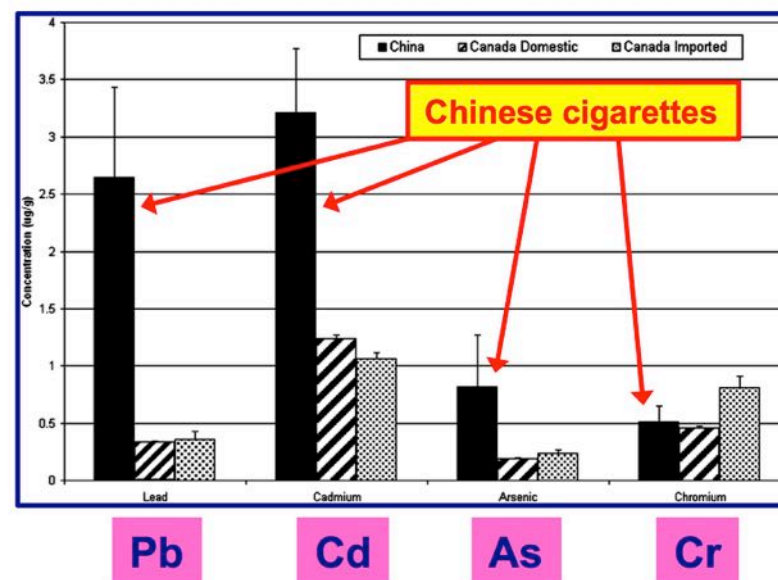
Methods: Mouth-level exposure to 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK) measured in cigarette butts and urinary concentrations of its major metabolite 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanol (NNAL) were examined among 126 daily smokers in four countries over a 24-hour study period.

Results: As mouth-level exposure of NNK increased, the urinary NNAL increased even after adjustment for other covariates ($\beta = 0.46$, $P = 0.004$). The relationship between mouth-level exposure to nicotine and its salivary metabolite, cotinine, was not statistically significant ($\beta = 0.29$, $P = 0.057$), likely because of the very limited range of differences in mouth-level nicotine exposure in this population.

Conclusions: We have shown a direct association between the 24-hour mouth-level exposure of NNK resulting from cigarette smoking and the concentration of its primary metabolite, NNAL, in the urine of smokers. Internal dose concentrations of urinary NNAL are significantly lower in smokers in countries that have lower TSNA levels in cigarettes such as Canada and Australia in contrast to countries that have high levels of these carcinogens in cigarettes, such as the United States.

Impact: Lowering the levels of NNK in the mainstream smoke of cigarettes through the use of specific tobacco types and known curing practices can significantly affect the exposure of smokers to this known carcinogen. *Cancer Epidemiol Biomarkers Prev*; 19(6); 1389–98. ©2010 AACR.

Chinese cigarettes contain 3 times the levels of heavy metals (Pb, Cd, As) of Canadian cigarettes



O'Connor RJ et al. *Tob Control*. 2010 Oct; 19 Suppl 2:i47-53.



International Tobacco Control
Policy Evaluation Project

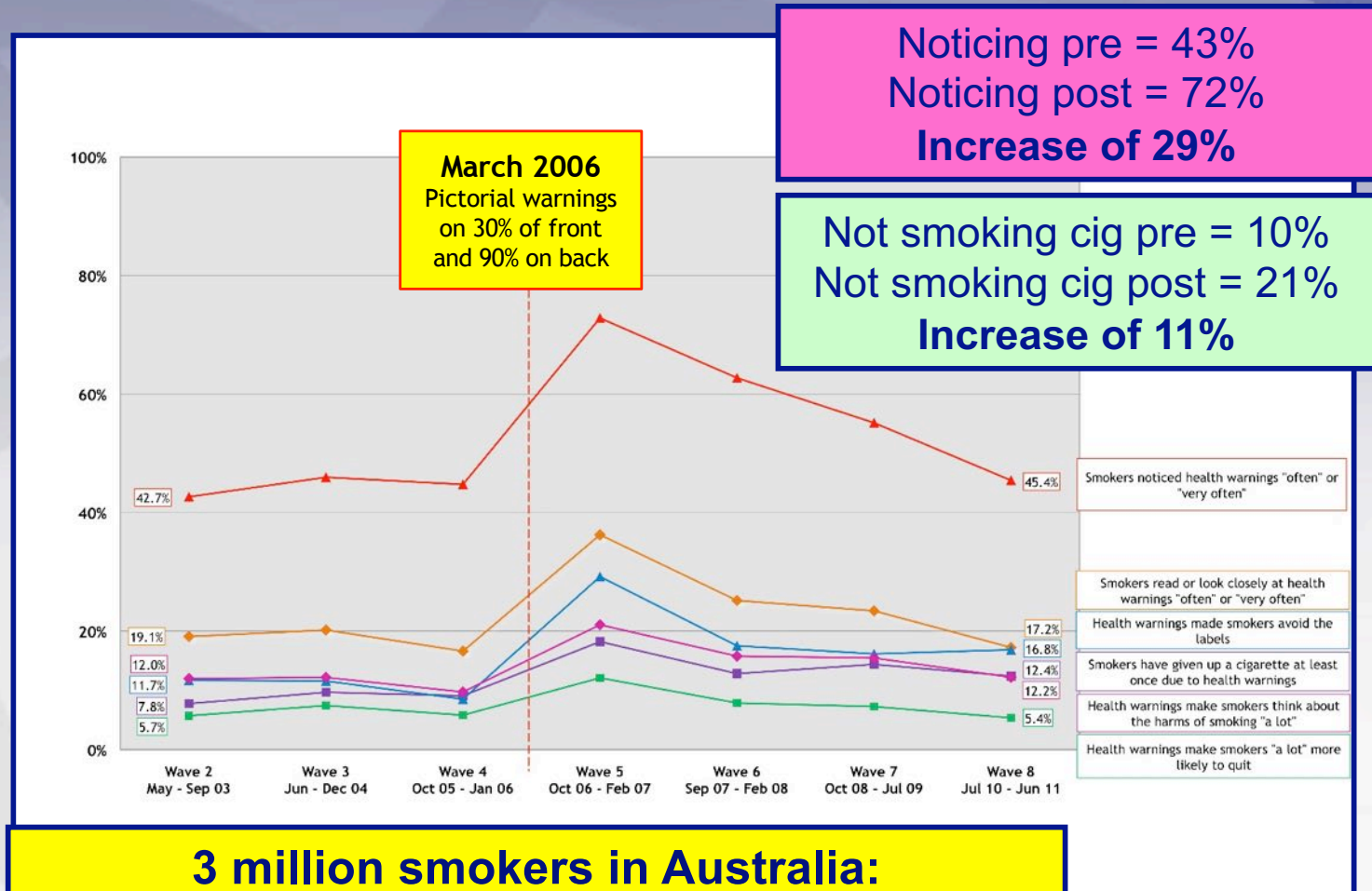
Evaluating FCTC Policies: Graphic Health Warnings

Measures of Effectiveness for Health Warnings

ITC Surveys include 6 key indicators of warning effectiveness:

1. How often respondents **notice the warnings**
2. How often respondents have **closely read the warnings**
3. How much the warnings make respondents **think about the health risks of smoking**
4. How much the warnings make them **more likely to quit**
5. If the smoker has made any effort to **avoid the warnings**
6. If the warnings have **stopped the smoker from having a cigarette** in the last month

Australia: March 2006 (30% front, 90% back)



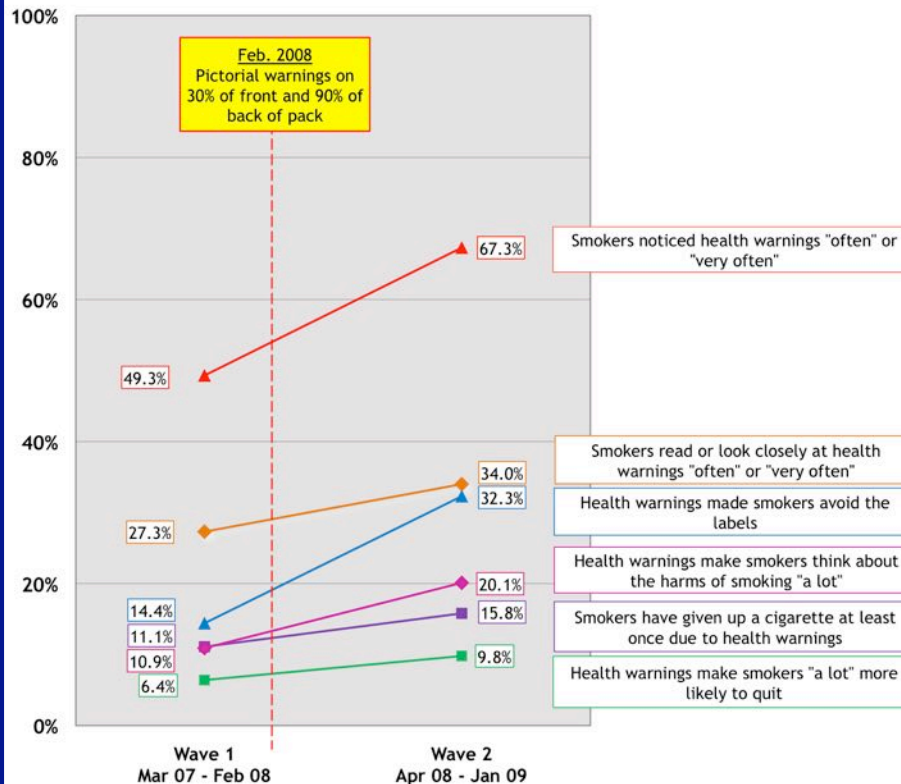
3 million smokers in Australia:
After the introduction of pictorial warnings:

- 870,000 more smokers noticed the warnings
- 330,000 more smokers reported not smoking a cigarette because of the warnings

New Zealand: February 2008 (30% front, 90% back)



Impact of health warnings on male smokers' perceptions and behaviours at the first wave vs. the most recent wave in New Zealand



Noticing pre= 49.3%
Noticing post= 67.3%
Increase of 18.0%

Forgoing cig pre = 10.9%
Forgoing cig post = 15.8%
Increase of 4.9%

650,000 smokers in New Zealand

After the introduction of pictorial warnings:

- 117,000 more smokers noticed the warnings
- 30,550 more smokers reported forgoing a cigarette because of the warnings



International Tobacco Control
Policy Evaluation Project

Using ITC evaluation data to call attention to the need for stronger warnings in China

Key stakeholders:

China CDC: Jiang Yuan (Deputy Director of TC)

WHO China: Bernhard Schwartlander (WR),
Angela Pratt / Kelvin Khaw (TFI)

Campaign for Tobacco-Free Kids: Xi Yin and others

ThinkTank: Wang Ke'an

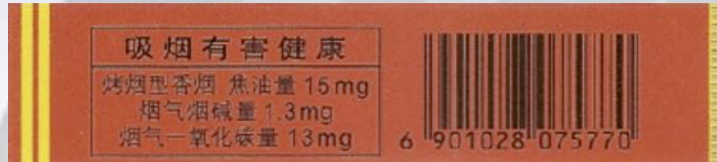
Other important supporters: Judith Mackay

The lower effectiveness of text-only health warnings in China compared to pictorial health warnings in Malaysia

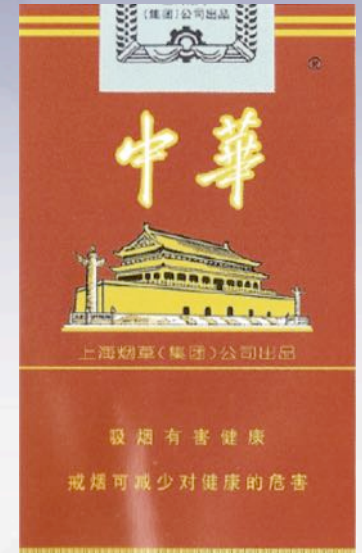
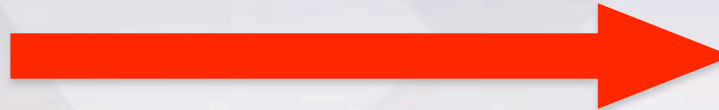
Tara Elton-Marshall,^{1,2} Steve Shaowei Xu,³ Gang Meng,³ Anne C K Quah,³ Genevieve C Sansone,³ Guoze Feng,⁴ Yuan Jiang,⁴ Pete Driezen,³ Maizurah Omar,⁵ Rahmat Awang,⁵ Geoffrey T Fong^{3,6,7}

Tobacco Control (2015); 24: iv6-iv13.

In 2008, China & Malaysia had the same poor text-only warnings...



**2009
China stayed text-only**



**2009
Malaysia went to graphic**

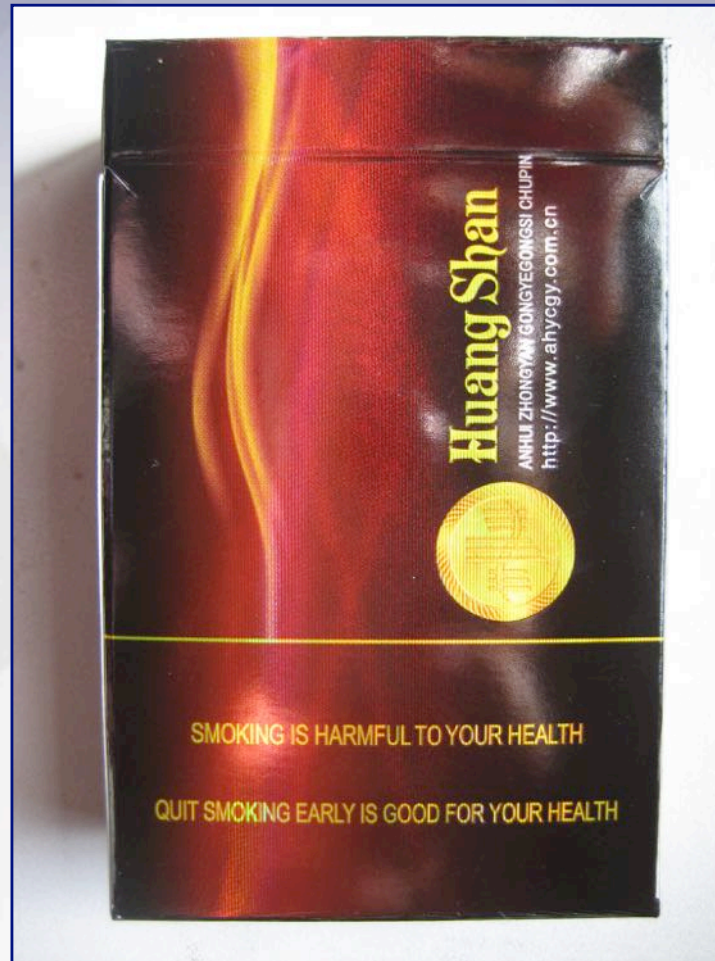


China's 2009 warnings: front and back

Front of pack



Back of pack



**Warnings appear in English
on the back of every pack!!**

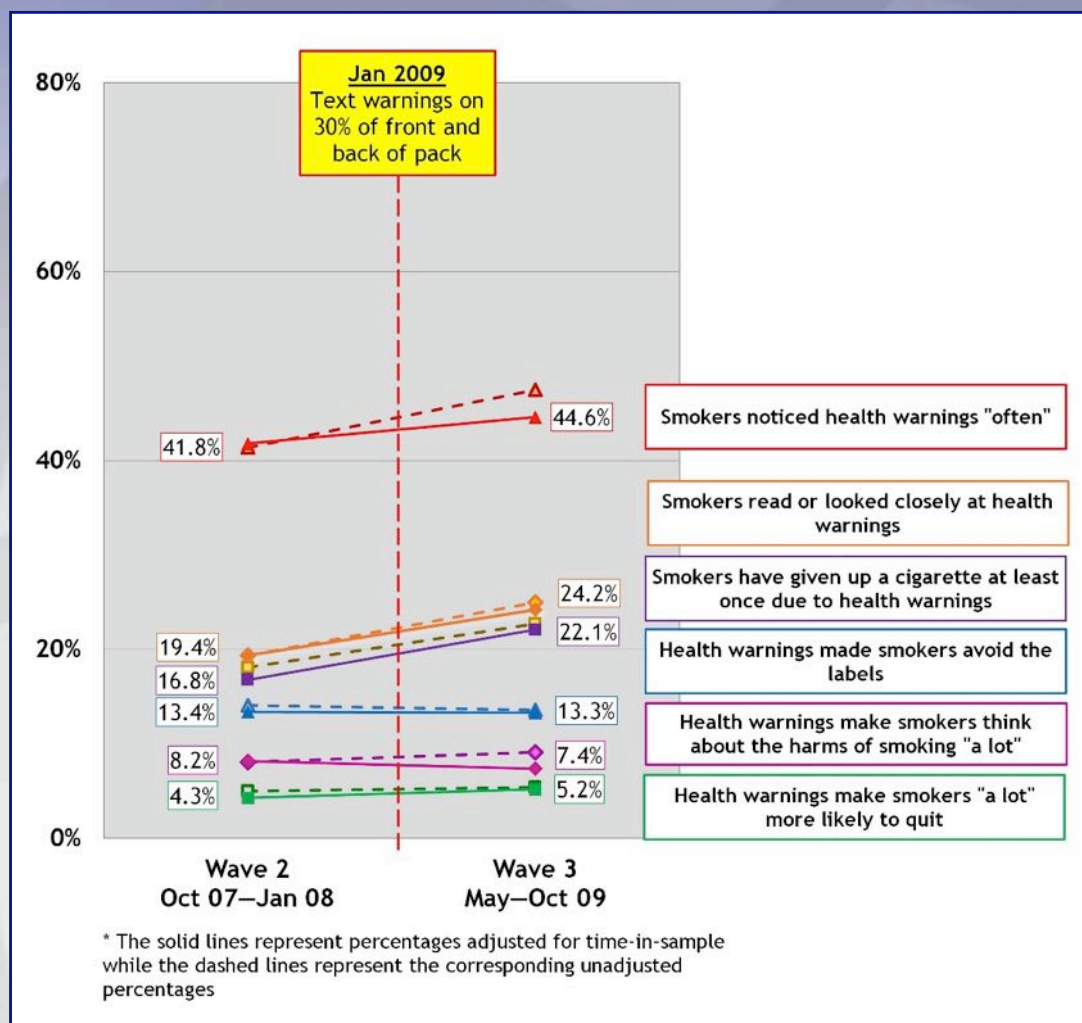
Perceptions of tobacco health warnings in China compared with picture and text-only health warnings from other countries: an experimental study

Geoffrey T Fong,^{1,2} David Hammond,¹ Yuan Jiang,³ Qiang Li,^{1,3} Anne C K Quah,¹ Pete Driezen,¹ Mi Yan,¹ for the ITC China Project Team

Fewer than 10% of adult smokers understood the English warnings

smokers could not translate one of the two sentences on the text-only warning, and close to 90% of them could not translate the other sentence. These findings support the principle that countries should not be presenting important health messages to their people in a foreign language.

ITC Evaluation: China's Jan 2009 Text-Only Revision



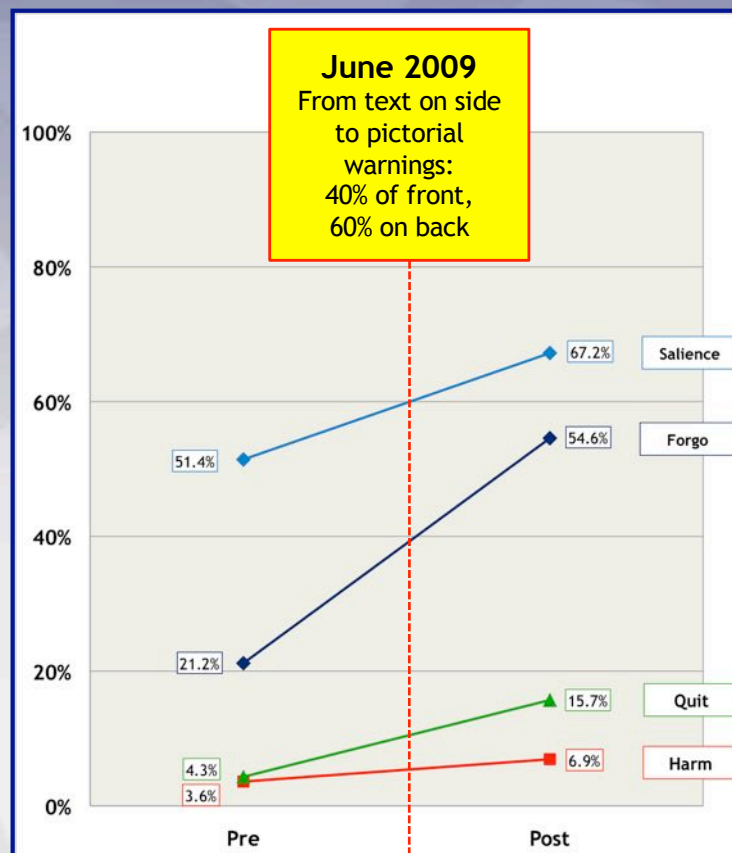
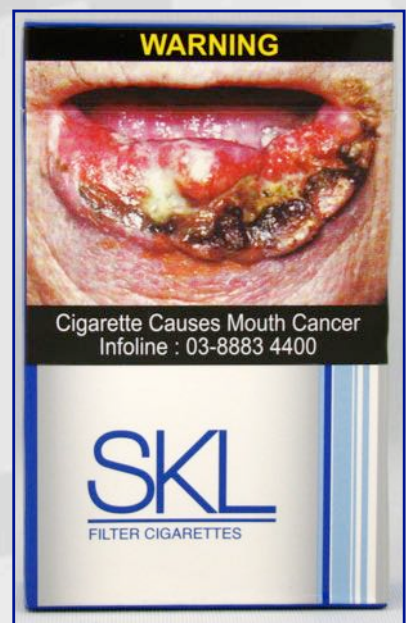
Noticing pre = 41.8%
Noticing post = 44.6%
Increase of 2.8%

Forgoing cig pre = 16.8%
Forgoing cig post = 22.1%
Increase of 5.3%

About 300 million smokers in China:

- 8.4 million more smokers noticed the warnings
- 15.9 million more smokers reported forgoing a cigarette because of the warnings

Malaysia: June 2009 (40% front, 60% back)



Noticing pre = 51.4%
Noticing post = 67.2%
Increase of 15.8%

Not smoking cig pre = 21.2%
Not smoking cig post = 54.6%
Increase of 33.4%

3.6 million smokers in Malaysia
After the introduction of pictorial warnings:

- 569,000 more smokers noticed the warnings
- 1,202,400 more smokers reported not smoking a cigarette because of the warnings

If China implemented Malaysia's graphic warnings...

9.5% x 300M = **28.5 million more smokers** would have
noticed the warnings often

8.4% x 300M = **25.2 million more smokers** would have
read the warnings closely

4.4% x 300M = **13.2 million more smokers** would have
reported that the **warnings made them think**
about the health risks of smoking

7.7% x 300M = **23.1 million more smokers** would have
reported that the **warnings made them think**
about quitting

17.6% x 300M = **52.8 million more smokers** would have
reported that the **warnings had stopped them**
from smoking a cigarette at least once

Release of WHO/ITC China Warnings Report April 2014

Tobacco health warnings in China

EVIDENCE OF EFFECTIVENESS AND IMPLICATIONS FOR ACTION



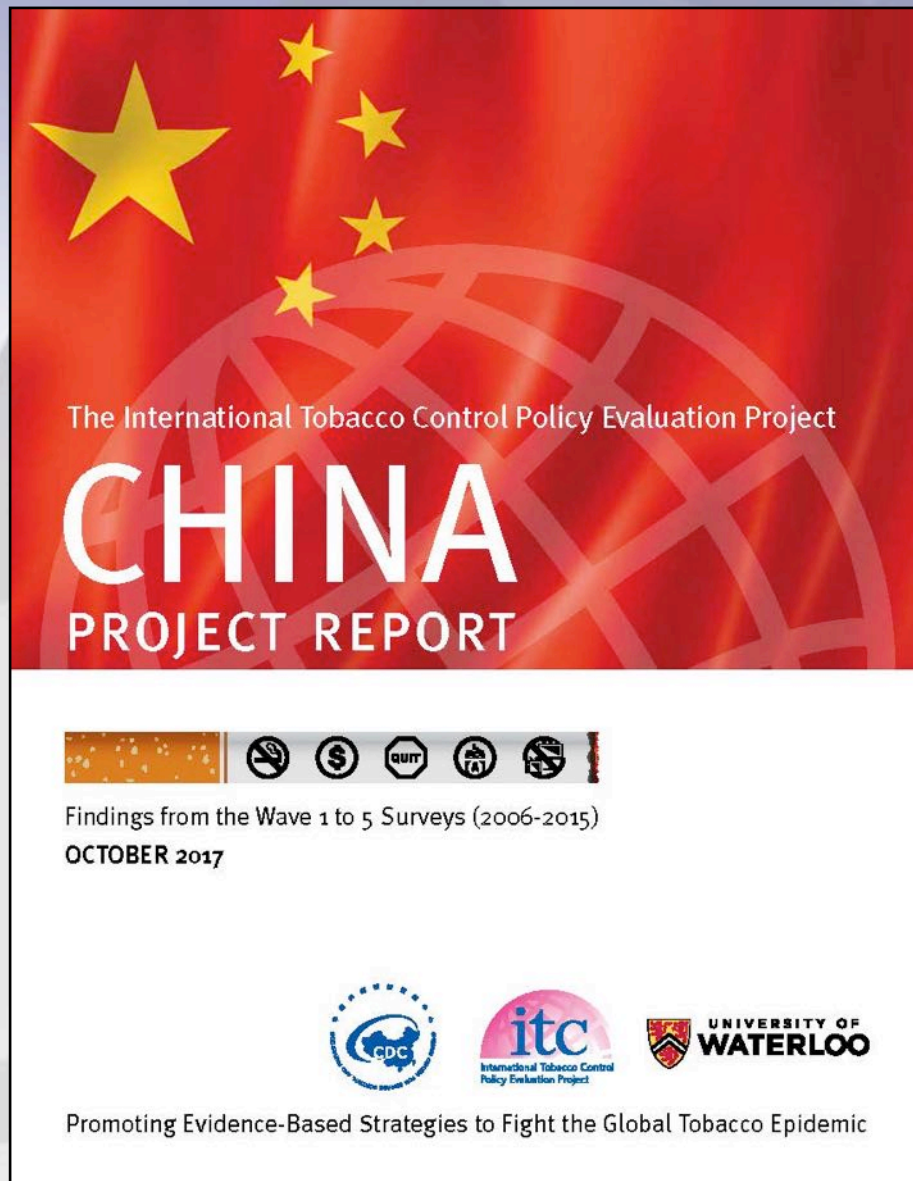
ITC National Reports: China (Dec 2012)



China Report released in Beijing in Dec 2012 at the Chinese Communist Party School and at the China NCD Forum



ITC China Wave 1 to 5 Project Report



ITC China Project Report

- ◆ Findings from five survey waves in China: covers a 9-year time period: April 2006 to July 2015
- ◆ Includes comparisons with other ITC countries

Direct dissemination through submissions

US FDA: Graphic warnings

Submission to Docket No. FDA-2010-N-0568

Required Warnings for Cigarette Packages and Advertisements

January 11, 2011

Geoffrey T. Fong, Ph.D.

Professor of Psychology, University of Waterloo, Waterloo, Ontario, Canada

Senior Investigator, Ontario Institute for Cancer Research, Toronto, Ontario, Canada

Hong Kong: Larger warnings



EFFECTIVENESS OF LARGE PICTORIAL HEALTH WARNINGS ON
TOBACCO PACKAGES: A REVIEW OF THE GLOBAL EVIDENCE

Submission to the Government of Hong Kong

December 22, 2016

Uruguay: Plain packaging



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November 2, 2016

The Honourable Dr. Jorge Basso
Minister of Public Health
Oriental Republic of Uruguay

Cc: Dr. J Vidal, Dr. E. Soto, Dr. Eduardo Bianco

**RE: Plain Packaging and the International Tobacco Control Policy Evaluation Project
(the ITC Project)**

Dear Honourable Minister:

I am writing as the Chief Principal Investigator of the International Tobacco Control Policy Evaluation (ITC) Project at the suggestion of Dr. Eduardo Bianco, regarding Uruguay's objective of adopting and implementing plain standardized packaging on tobacco products.

Canada: Plain packaging

CONSULTATION ON "PLAIN AND STANDARDIZED" PACKAGING
FOR TOBACCO PRODUCTS

Submission by the International Tobacco Control Policy
Evaluation Project, University of Waterloo

August 31, 2016

...and testimony...



Federal tobacco strategy turns from scary labels to stopping contraband

GLORIA GALLOWAY

Ottawa— From Tuesday's Globe and Mail

Published Tuesday, Sep. 28, 2010 3:00AM EDT

Last updated Monday, Jan. 10, 2011 1:26PM EST

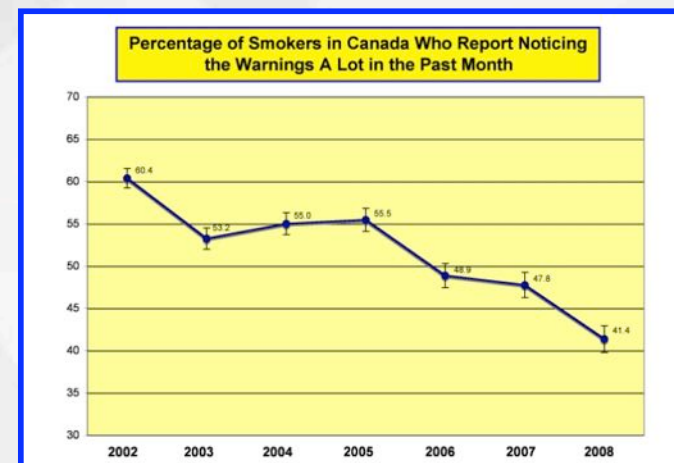
Sep 28, 2010: Health Canada announces that the ongoing initiative to revise the 10-year-old tobacco warnings is being shelved



Dec 30, 2010: Health Minister reverses decision—the revision of the warnings will continue. New warnings have been introduced in 2012.



Dec 9, 2010: Hearing held by the House of Commons Health Committee on the Govt's decision to shelve the revision.

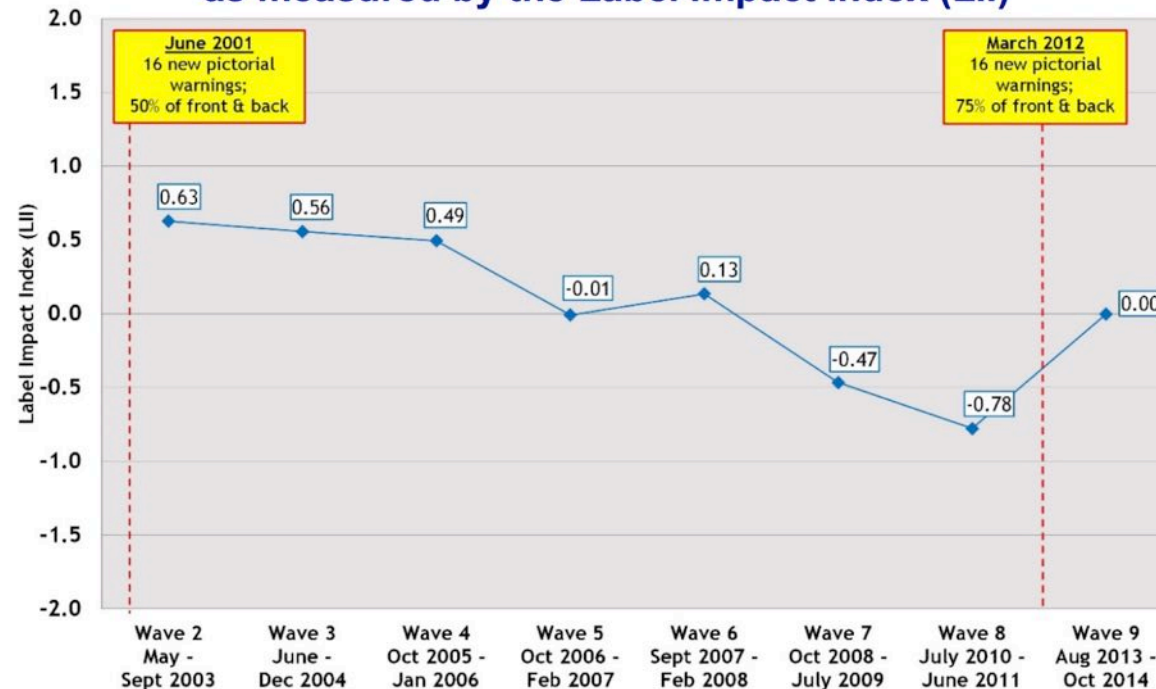


ITC Canada Survey data show that every indicator of label impact has declined dramatically over the past 7 years

Impact of 2012 revision of warnings

- ITC survey: Steady decline in warning impact from 2003-2011, but then a substantial increase with the 2012 revision.

Decrease in impact of 50% pictorial warnings in Canada over time, as measured by the Label Impact Index (LII)



Note: Results are adjusted for age, sex, smoking status (daily/non-daily), and time-in-sample effects. The Label Impact Index (LII) was calculated by normalizing scores on four measures of warning label impact (noticing warnings, thinking about harms and thinking about quitting because of warnings, and forgoing a cigarette because of warnings), and forming a weighted composite. Scores were then added together such that $LII = (salience \times 1) + (harm \times 2) + (quitting \times 2) + (forgo \times 3)$. Higher scores on the LII represent greater warning label impact.



2012



International Tobacco Control
Policy Evaluation Project

Research showing that a policy works (without adverse side effects) Ireland's comprehensive smoke-free law

**Key stakeholders in Ireland—ITC Ireland co-investigators
(researchers and advocates):**

Fenton Howell, Luke Clancy, Shane Allwright, Maurice Mulcahy

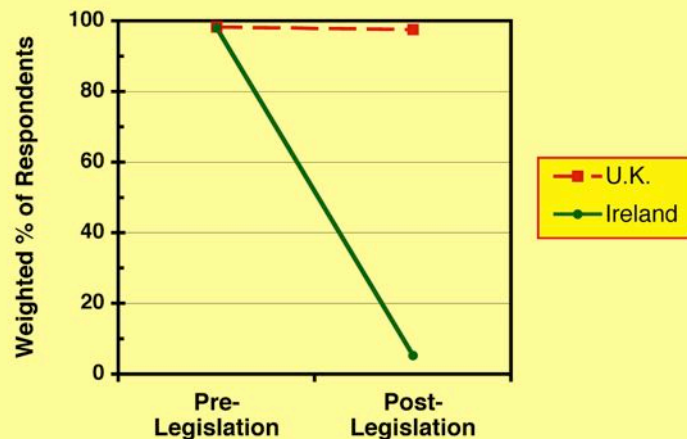
RESEARCH PAPER

Reductions in tobacco smoke pollution and increases in support for smoke-free public places following the implementation of comprehensive smoke-free workplace legislation in the Republic of Ireland: findings from the ITC Ireland/UK Survey

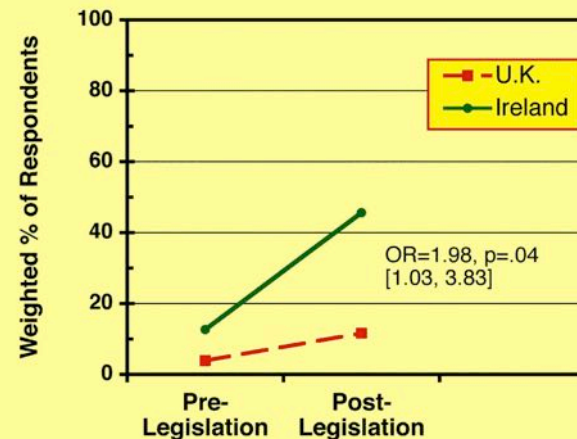
G T Fong, A Hyland, R Borland, D Hammond, G Hastings, A McNeill, S Anderson, K M Cummings, S Allwright, M Mulcahy, F Howell, L Clancy, M E Thompson, G Connolly, P Driezen

Tobacco Control 2006;15(Suppl III):iii51–iii58. doi: 10.1136/tc.2005.013649

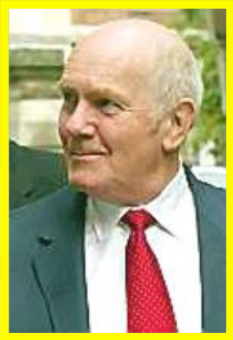
Reported Smoking in Bars/Pubs—Last Visit



Support for Total Ban in Bars/Pubs



Smoke-free pubs lead to smoke-filled homes?



John Reid, former U.K. Secretary of State for Health, at a House of Commons Health Committee Evidence Hearing, Feb. 23, 2005:

*In Scotland, for instance, they have decided to go for a complete ban on smoking. I came to the conclusion that that was not a good thing on health grounds, apart from anything else, **because you get a displacement of smoking from some public areas to the home** - and most of the evidence about passive smoking is about the home...*

*...what we do know, for instance in Ireland and we would anticipate in Scotland, is that a percentage of people who previously went to the pub to smoke will now get a carry-out and take it home. **I think the percentage in Ireland is about 15 per cent.***

**But ITC Ireland Survey refuted Reid's claim:
the percentage of smokers who banned smoking
inside their homes increased after the ban!**

Dissemination of ITC Ireland Findings Directly to Policymakers

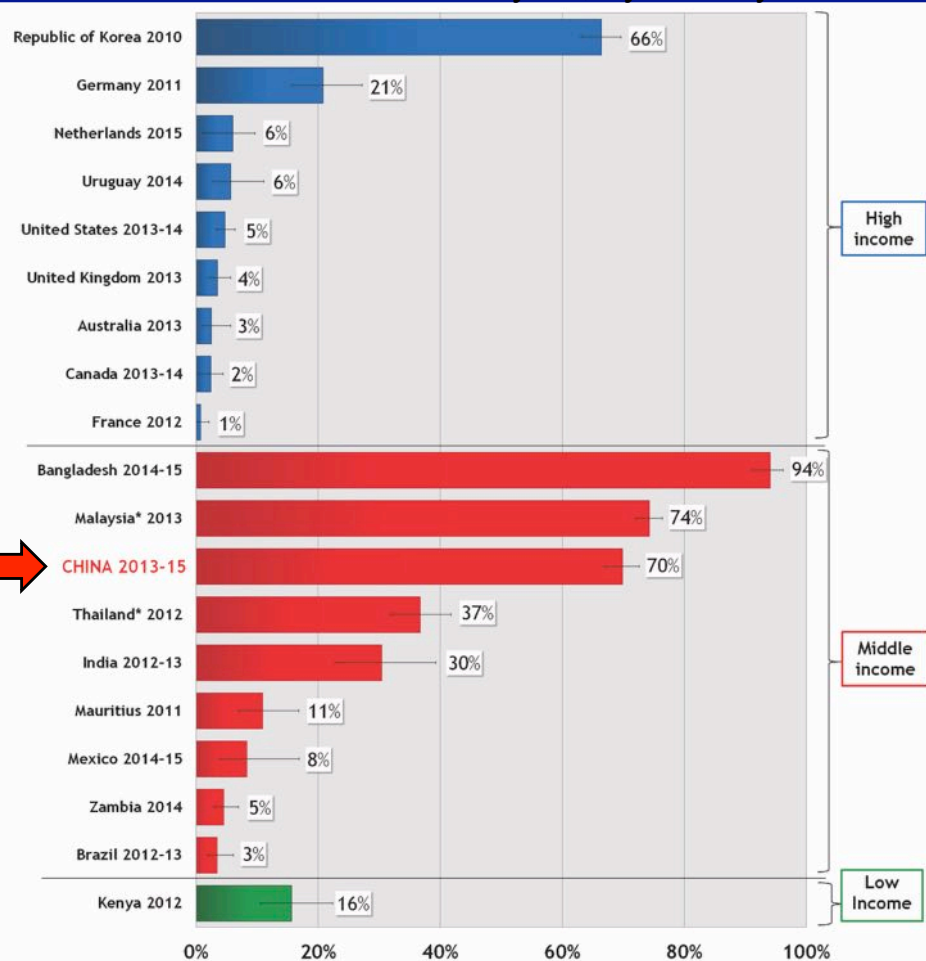
European Smoke-Free Meeting, Luxembourg, June 2005:
High-level meeting of policymakers:

- Former Irish Minister of Health and Children, Micheál Martin
- Former Health Minister of Italy
- Health Ministers from Sweden, Finland, Latvia, Cyprus, Hungary, Malta, and Luxembourg
- Under-Secretary of State of Poland
- European Commission Director-General for Health and Consumer Protection
- Lord Faulkner of Worcester, House of Lords, United Kingdom
- Several undersecretaries/deputy ministers of health
- Several members of the European Parliament.

**Led to advancing the agenda on smoke-free
throughout the European Union**

Prevalence of smoking in restaurants China compared to 18 other ITC countries

Percentage of male smokers and quitters who noticed smoking in restaurants, among those who visited a restaurant in the last year, by country

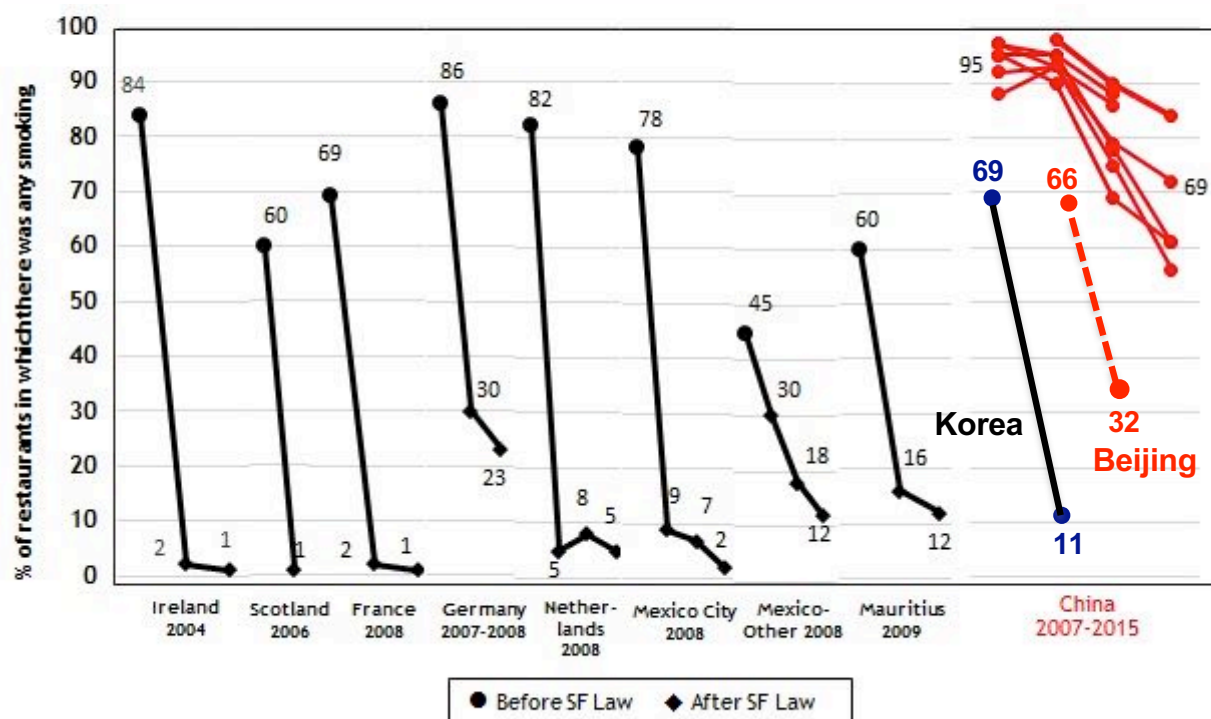


* In Malaysia and Thailand, the results are the average between indoor air-conditioned restaurants and the non-smoking areas of non-air-conditioned/outdoor restaurants.

- China still has the 3rd highest percentage of restaurants with smoking (70%) among 19 ITC countries

Smoking in Restaurants

Smoking Prevalence observed in restaurants in 7 ITC China cities from Wave 2 to 5 (2007 to 2015) compared to other countries before and after comprehensive smoke-free laws: Ireland (2004), Scotland (2006), France (2008), Germany (2007-08), Netherlands (2008), Mexico City (2008), Other Mexican Cities (2008), and Mauritius (2009)



- The decrease in restaurant smoking in China is **much smaller** than in other ITC countries with **comprehensive** smoke-free laws

Beijing's comprehensive smoke-free law has led to significant reductions in smoking in restaurants (report from Beijing CDC, Dec 2016)

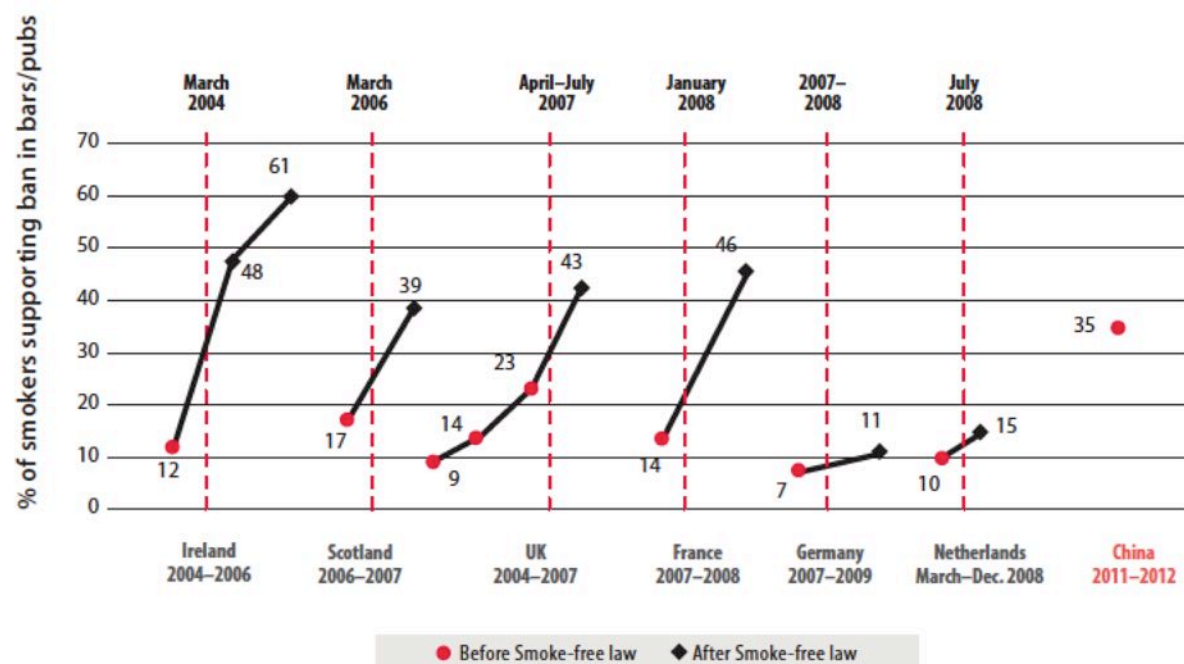
Note: the percentage shown for Republic of Korea in 2016 is based on a preliminary, unweighted, and unadjusted dataset

Strong Article 8 implementation leads to dramatic decreases in tobacco smoke in public areas

Support for smoking bans in bars

Pre-post in 6 ITC countries + China

FIGURE 15. Support among smokers for bans in bars/pubs in China (2011–2012) compared with other countries



Note: The percentage for China represents the average across the cities

Support for smoking bans among smokers is MUCH higher in China than it was in other countries before *their successful smoking bans.*



International Tobacco Control
Policy Evaluation Project

Research guiding policymakers to NOT do the WRONG thing!

Kenya: tax structure

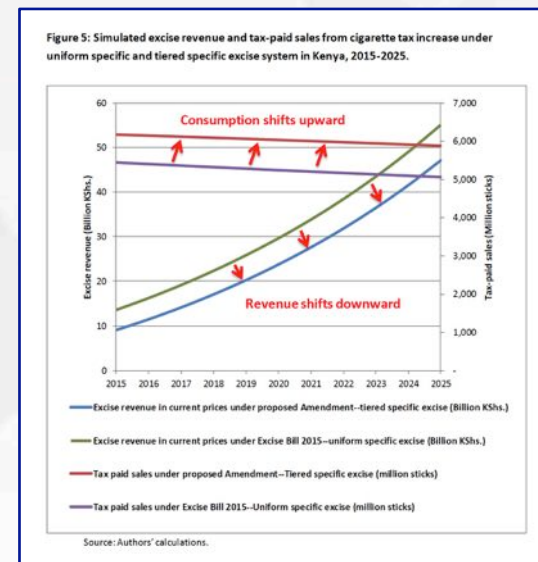
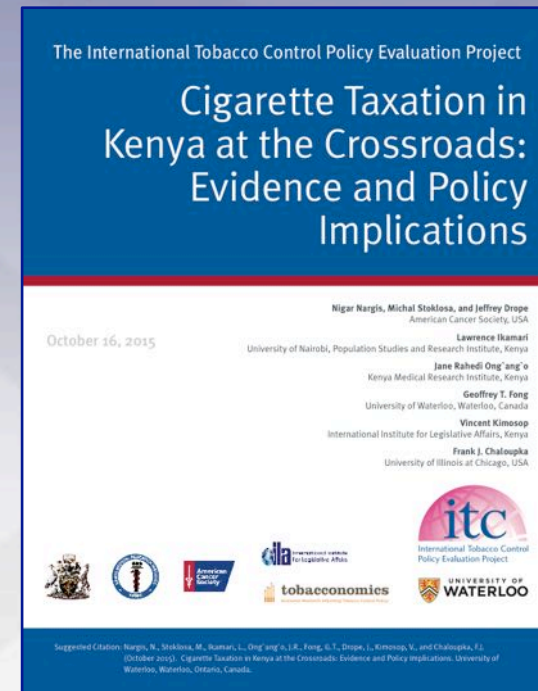
Key stakeholders in Kenya:

Lawrence Ikamari (U Nairobi) and Jane Ong'ang'o (KEMRI)
Dorcas Kiptui (MOH) and Vincent Kimosop (ILA-NGO)

Kenya: Do not go back to tiered tax structure

1. Kenyan Parliament proposed to return to a tiered tax structure.
2. President was advised to stay with the more efficient and effective untiered structure.
3. Dissemination: prepared a detailed report on the negative consequences of returning to the tiered tax structure.
4. Sent the report and letter to the President.

Outcome: The President prevailed.



Release of ITC Kenya National Report–Dec 2015

The International Tobacco Control Policy Evaluation Project

ITC Kenya National Report

FINDINGS FROM THE WAVE 1 (2012) SURVEY
DECEMBER 2015

Promoting Evidence-Based Strategies to Fight the Global Tobacco Epidemic

UNIVERSITY OF NAIROBI

IILA International Institute for Legislative Affairs

Ministry of Health

KEMRI

itc International Tobacco Control Policy Evaluation Project

UNIVERSITY OF WATERLOO





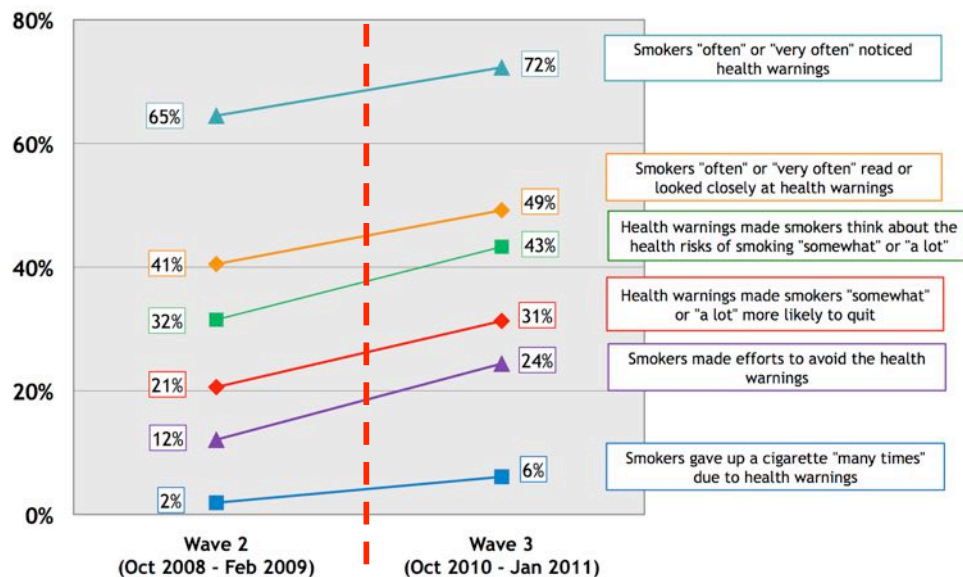
Using ITC Project Data to Defend Against Tobacco Industry Challenges

- 1. Uruguay: bilateral investment treaty**
- 2. Australia: World Trade Organization**

PMI challenges Uruguay's warning size increase

Philip Morris International challenges Uruguay's increase in warning size from 50% to 80% via a bilateral trade agreement. PMI claims that there's no evidence that increasing warning size above 50% (Article 11 Guidelines) is more effective.

Impact of health warning labels in Uruguay on salience, perceptions and behaviours pre-policy (Wave 2) and post-policy (Wave 3)



Gravely et al., 2016 (Tob Control)

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

Shannon Gravely,¹ Geoffrey T Fong,^{1,2,3} Pete Driezen,¹ Mary McNally,¹ James F Thrasher,⁴ Mary E Thompson,⁵ Marcelo Boado,⁶ Eduardo Bianco,⁷ Ron Borland,⁸ David Hammond²

Conclusion: increasing warning size increases effectiveness.

Size increased
from 50% to 80%

OPINION | LATIN AMERICA

Big Tobacco Gets Crushed by Tiny Uruguay

Philip Morris's failed attempt to use trade agreements to block anti-smoking rules clears the way for other countries.

- ◆ Trade treaty panel rules against PMI on all counts
- ◆ PMI required to pay all court costs + \$7M to Uruguay for its legal costs



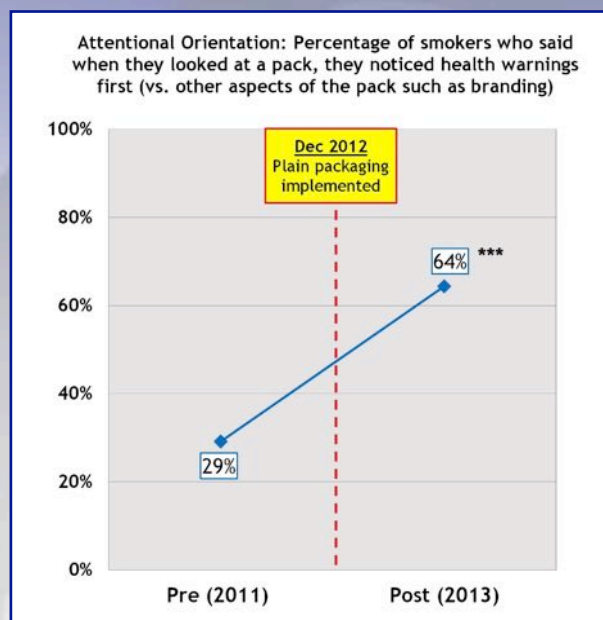
Australia: Evidence used to defend plain packaging against WTO challenge

Industry challenges Australia's plain packaging

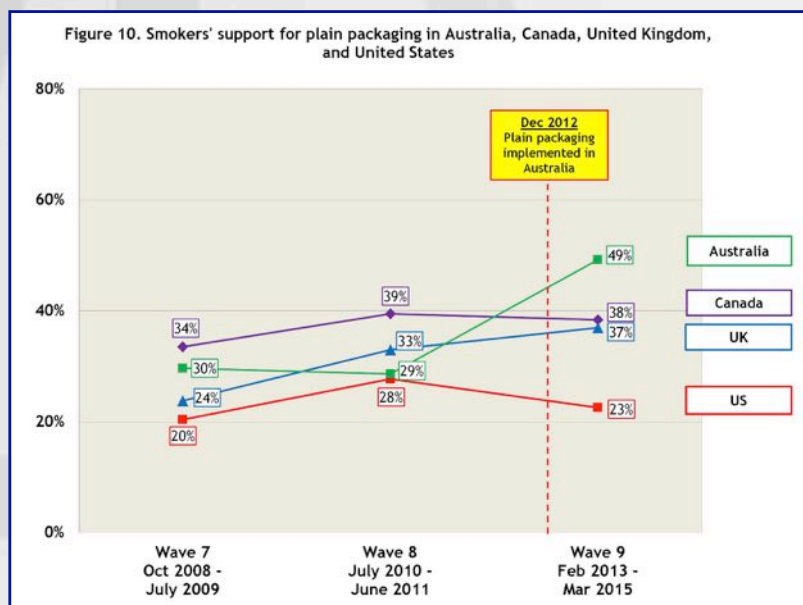
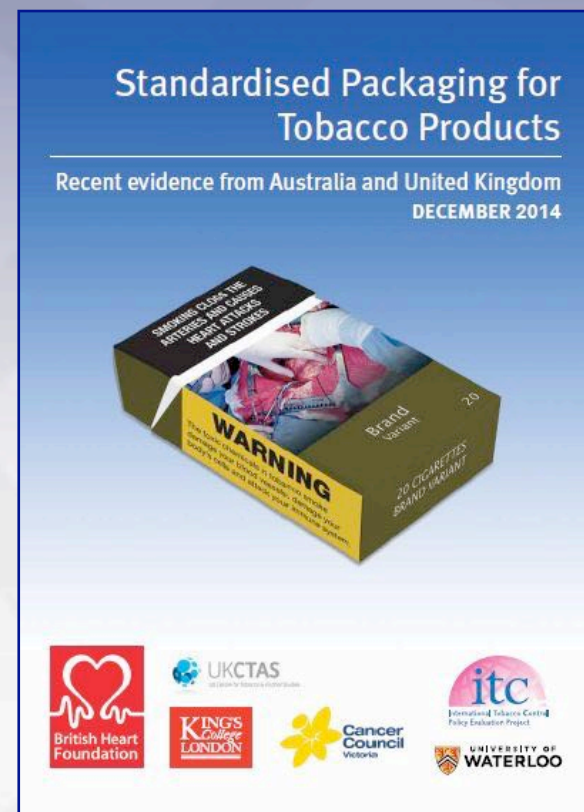
1. **Constitutional challenge:** Australia wins in High Court, 6-1.
2. **Bilateral Investment Treaty:** Philip Morris Asia (based in Hong Kong) challenges via Hong Kong-Australia BIT
3. **World Trade Organization:** Challenge from Honduras, Dominican Republic, Cuba, and Indonesia. Over 40 countries expressed interests in this dispute: largest number ever for a WTO dispute.



ITC Evidence on Australia Plain Packaging



Yong et al. (2016):
plain packaging
significantly increased
health warning
effectiveness



Swift et al. (2014):
Smokers' support for
plain packaging rose
significantly after
implementation





Australia wins landmark WTO dispute on tobacco packaging

(CNN) — Australia has won a landmark victory at the World Trade Organization (WTO), which found that the country's stringent laws requiring plain packaging on tobacco products do not violate the country's trade obligations.



WORLD TRADE
ORGANIZATION

**WT/DS435/R, WT/DS441/R
WT/DS458/R, WT/DS467/R**

28 June 2018

(18-4061)

Page: 1/884

Original: English

AUSTRALIA – CERTAIN MEASURES CONCERNING TRADEMARKS, GEOGRAPHICAL INDICATIONS AND OTHER PLAIN PACKAGING REQUIREMENTS APPLICABLE TO TOBACCO PRODUCTS AND PACKAGING

REPORTS OF THE PANELS

Dissemination of lessons learned

- ◆ Research must be relevant to the policy agenda
- ◆ Research must be scientifically sound
- ◆ Research findings must be communicated in meaningful ways to different audiences (elected officials, bureaucrats, advocates, media)
- ◆ You're not an expert in politics—be humble.
- ◆ Essential to know the policy environment: how things work
- ◆ Who are the key stakeholders, and how do they relate to each other? Who has power and voice, and who doesn't? Who is willing to be a champion?
- ◆ Anticipate counter-arguments and have (simple) responses to each. Be aware of the industry.
- ◆ Reach out and collaborate with the advocates.

Framework Convention Alliance at COP8



Conclusions

- ◆ Population-level interventions are essential for tackling the global tobacco epidemic. Greatest importance: FCTC
- ◆ The FCTC works if implemented strongly, but implementation has been slow and weak throughout the world.
- ◆ Strong and full implementation of just the POWER policies could reduce global smoking prevalence by 315M.
- ◆ FCTC COP: Shifting from treaty building to implementation.
- ◆ Critically important need for evaluating the impact of policy implementation for (1) documenting the need for stronger policies, (2) providing feedback on the impact of new policies, (3) dispelling industry claims that there will be adverse impact of policies, (4) defending policies against legal challenges
- ◆ Dissemination of research evidence is essential—need for strong collaborations with civil society and/or with govt.

ITC Project Research Organizations



ITC Project Research Support



Core support provided by the
U.S. National Cancer Institute
(P01 CA200512)

Core support provided by a
Canadian Institutes of Health
Research Foundation Grant



Support for the ITC Project



US National Cancer Institute
Research Grants



Canadian Institutes of Health Research
Foundation Grant



Ontario Institute for Cancer Research
Senior Investigator Award



University of Waterloo
Office of Research

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www.itcproject.org