



International Tobacco Control
Policy Evaluation Project

The ITC Project: Evaluating the Impact of Tobacco Control Policies—Recent Findings on Health Warnings, Plain Packaging, and Canada's Menthol Ban

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University of Waterloo and
Ontario Institute for Cancer Research



Center for Research on Flavored Tobacco Products (CRoFT) Seminar, Univ of Rochester | July 13, 2020



Outline

- ◆ The global tobacco epidemic and the power of population interventions: policies and regulations
- ◆ WHO Framework Convention on Tobacco Control (FCTC)
- ◆ The need for **evidence systems** to evaluate and understand the impact of policies
- ◆ ITC Project: evidence system for policy evaluation
- ◆ Graphic health warnings
- ◆ Plain packaging
- ◆ Menthol ban in Canada
- ◆ Present/future: new nicotine products

Global Tobacco Epidemic

“Tobacco is the most effective agent of death ever developed and deployed on a worldwide scale.”

– John Seffrin, Past President,
American Cancer Society

- ◆ Over 1 billion tobacco users in the world
- ◆ Close to 7 million deaths per year
- ◆ 20th century: 100M deaths
- ◆ 21st century: 1 billion deaths
- ◆ Burden: shifting to low- and middle-income countries (LMICs)
- ◆ NOT just a health problem. Total economic cost of smoking = US\$1.4 trillion, equal to 1.8% of global GDP

Framework Convention on Tobacco Control (FCTC)

- ◆ Legally binding international treaty: first under the WHO
- ◆ Came into force in Feb 2005; now ratified by 181 countries
- ◆ Multisectoral: whole-of-government approach
- ◆ Includes broad range of tobacco control policies:
 - Pictorial warnings (Article 11)
 - Comprehensive smoke-free laws (Article 8)
 - Higher taxes to reduce demand (Article 6)
 - Bans/restrictions on marketing (Article 13)
 - Support for cessation (Article 14)
 - Measures to reduce illicit trade (Article 15; now a treaty)
 - Tobacco product regulation (Articles 9 and 10)
- ◆ Tobacco industry must be prevented from influencing policies and measures (Article 5.3)
- ◆ **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;

- ◆ 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)

Impact Assessment Supplement in Tobacco Control



Contents

Impact assessment of the WHO FCTC

- s79** Foreword by the Secretariat of the WHO Framework Convention on Tobacco Control

V L da Costa e Silva

- s81** Impact assessment of the WHO Framework Convention on Tobacco Control: introduction, general findings and discussion

P Puska, M Daube, WHO FCTC Impact Assessment Expert Group

- s84** Impact assessment of the WHO FCTC over its first decade: methodology of the expert group

G T Fong, J Chung-Hall, L Craig, for the WHO FCTC Impact Assessment Expert Group

- s89** The WHO FCTC and global governance: effects and implications for future global public health instruments

T F McInerney

- s94** Impact of implementation of the WHO FCTC on the tobacco industry's behaviour

S A Bialous

June 2019 Volume 28 Issue S2

- s97** Analysis of Article 6 (tax and price measures to reduce the demand for tobacco products) of the WHO Framework Convention on Tobacco Control

C van Walbeek, S Filby

- s104** Impact of the WHO FCTC on non-cigarette tobacco products

G S Zaatar, A Bazzi

- s113** The impact of the WHO Framework Convention on Tobacco Control in defending legal challenges to tobacco control measures

S Y Zhou, J D Liberman, E Ricafort

- s119** Impact of the WHO FCTC over the first decade: a global evidence review prepared for the Impact Assessment Expert Group

J Chung-Hall, L Craig, S Gravely, N Sansone, G T Fong

- s129** Impact of the WHO FCTC on tobacco control: perspectives from stakeholders in 12 countries

L Craig, G T Fong, J Chung-Hall, P Puska, for the WHO FCTC Impact Assessment Expert Group

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*

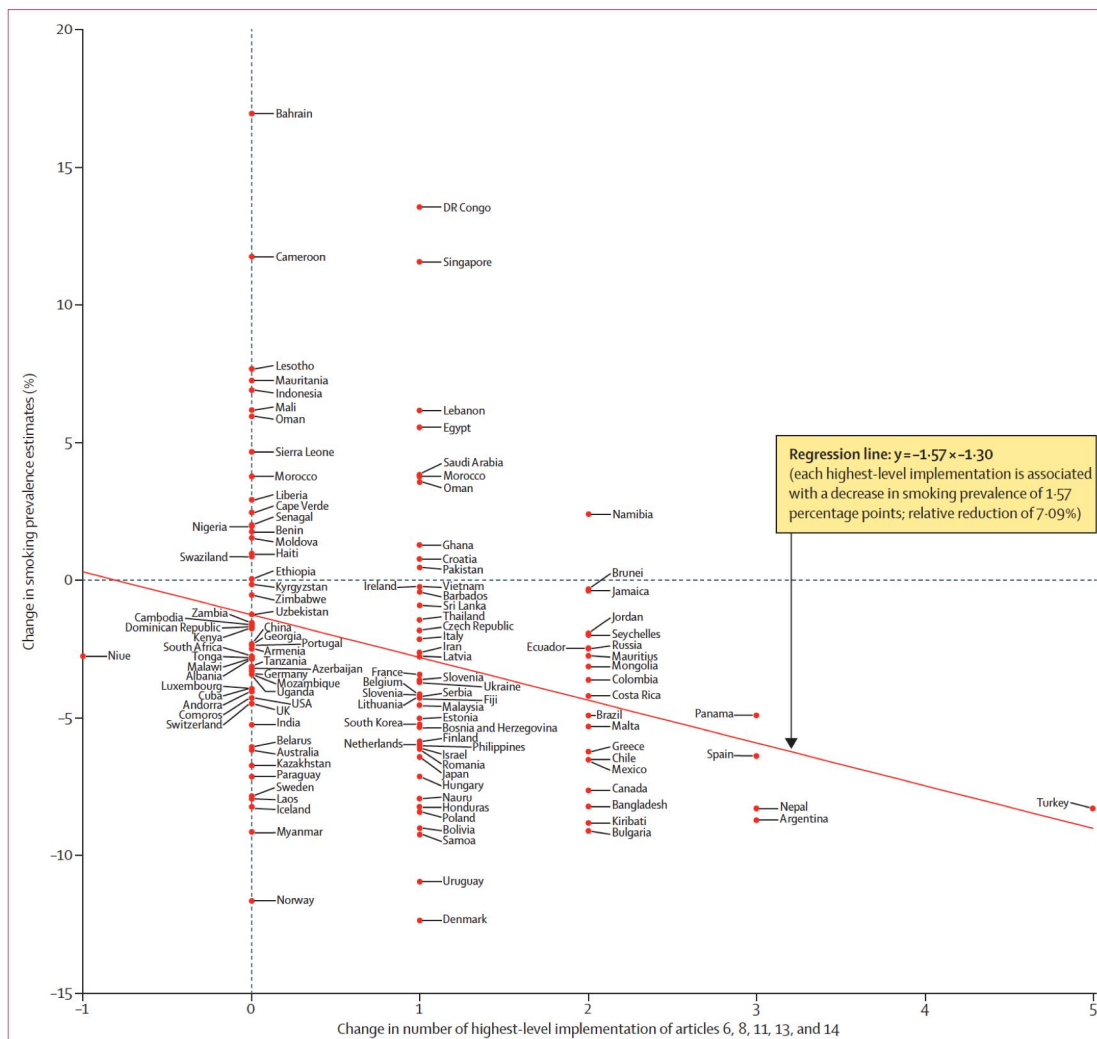


Figure 2: Relation between change in the number of five key WHO FCTC demand-reduction measures implemented at the highest level between 2007 and 2014 (x-axis) and change in smoking prevalence between 2005 and 2015 (y-axis)

- 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

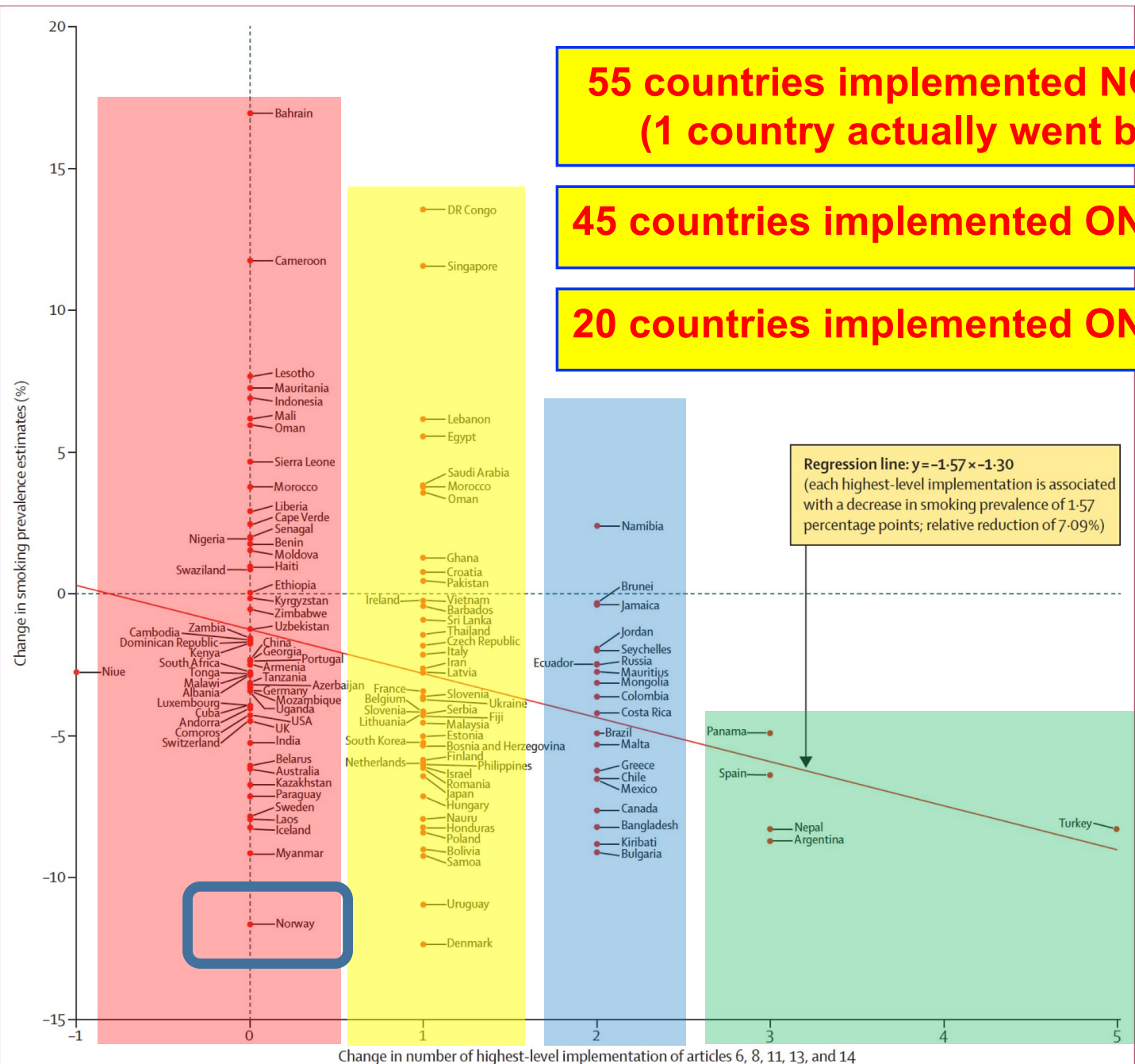


Figure 2: Relation between change in the number of five key WHO FCTC demand-reduction measures implemented at the highest level between 2007 and 2014 (x-axis) and change in smoking prevalence between 2005 and 2015 (y-axis)

| 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

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?**
 - 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
 - National surveillance systems

Tobacco 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 | |

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



Canada



United States



Australia



United Kingdom



Greece



Ireland



Thailand



Malaysia



Republic of Korea



Hungary



China



Uruguay



Mexico



New Zealand



Poland



France



Germany



Netherlands



Bangladesh



Romania



Brazil



Mauritius



Bhutan



India



Spain



Zambia



Kenya



Abu Dhabi



Japan

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 is necessary for smoke-free laws to work? Do smokers support smoke-free laws?
- ◆ 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)

ITC Project: 15th WCTOH (Singapore, 2012)

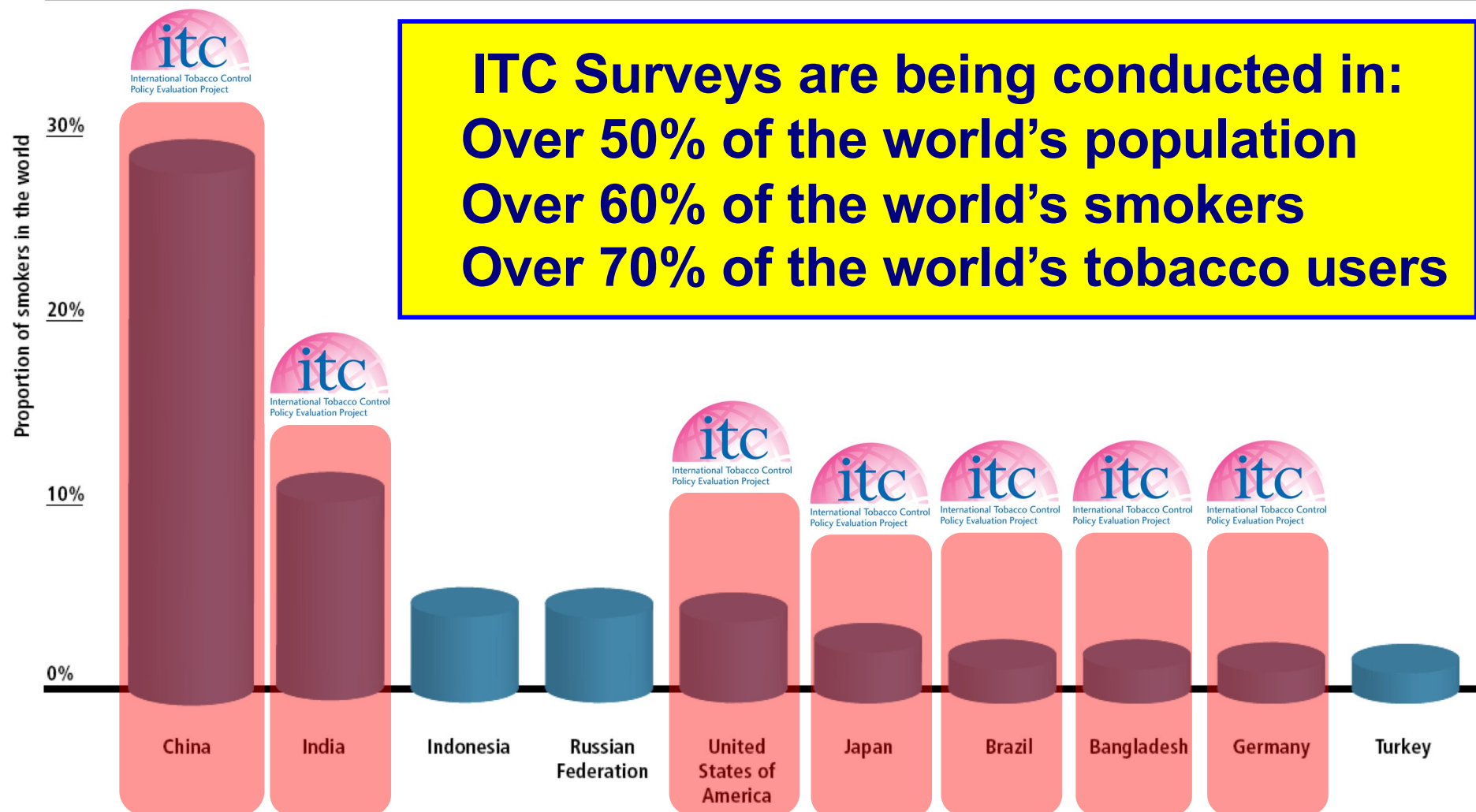


65 of our 100+ investigators and staff from 17 ITC countries

ITC is a Global Project...

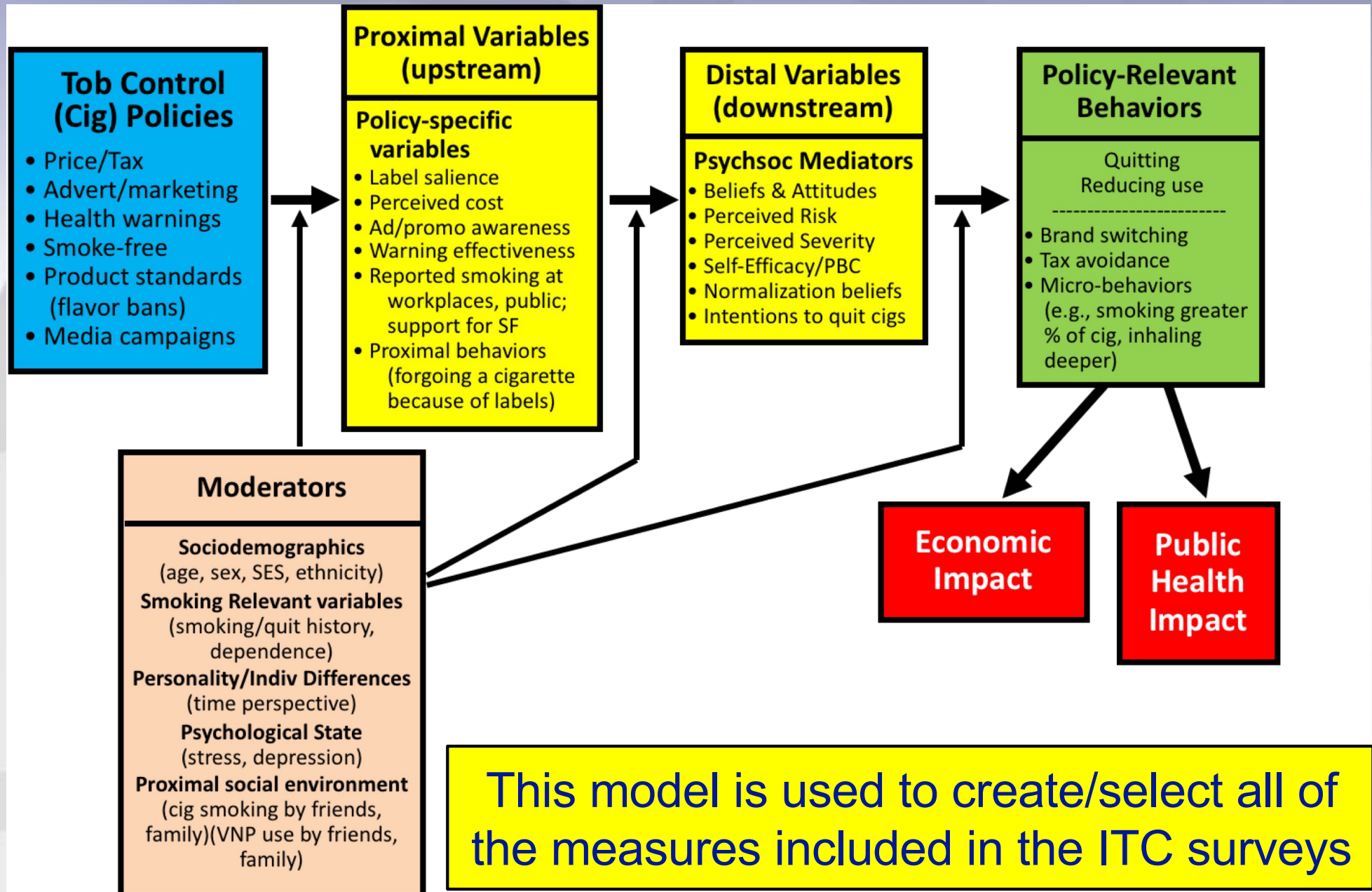


NEARLY TWO THIRDS OF THE WORLD'S SMOKERS LIVE IN 10 COUNTRIES



Source: The number of smokers per country was estimated using adjusted prevalence estimates (see Technical Note II and Appendix III). A limitation of this approach is that adjusted estimates used to estimate the number of smokers are sometimes derived from limited country data, and for some countries large adjustments are needed. In these cases the adjusted estimates can be different from actual surveys reported by countries. Brazil prevalence data were obtained from VIGITEL 2006.

ITC Conceptual Model: from TC policies to impact





PATH

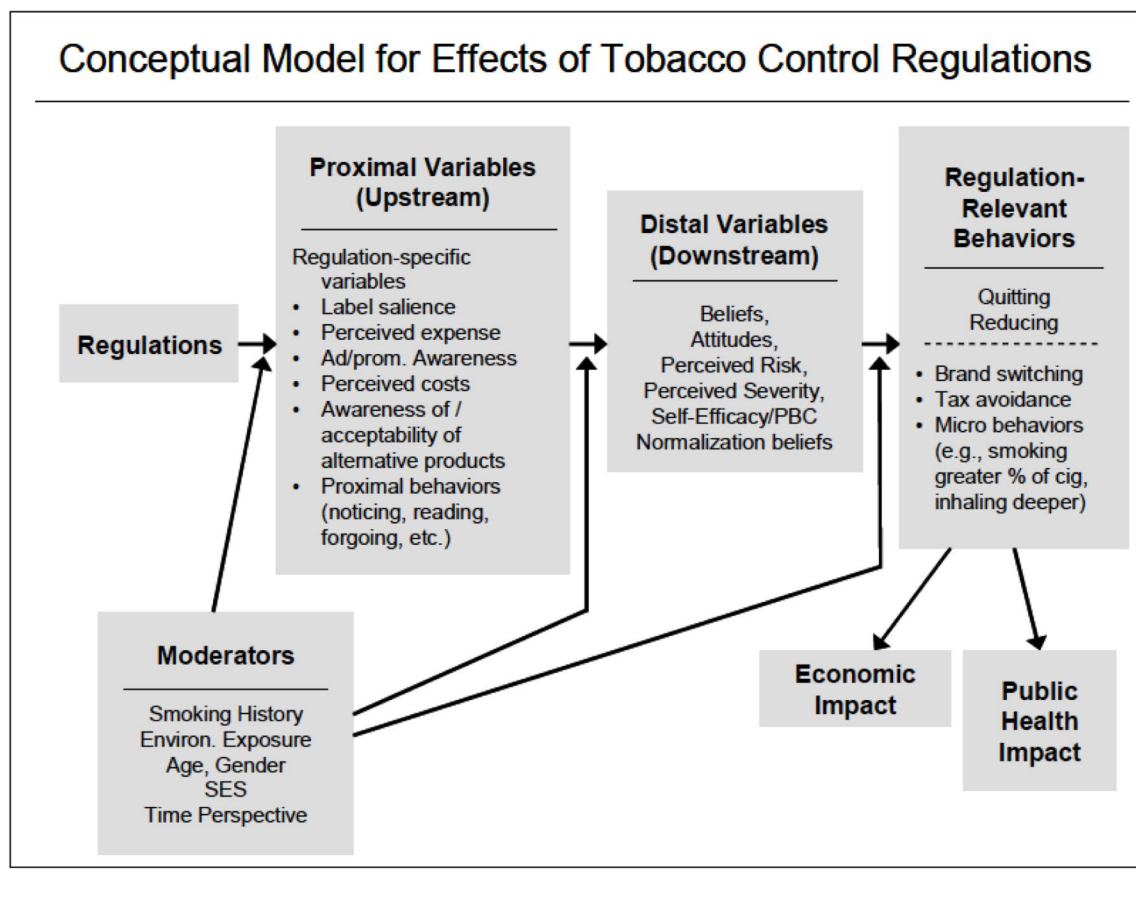
Population Assessment
of Tobacco and Health

A collaboration between the NIH and FDA

PATH Conceptual Model (from ITC)

1

Figure 1-2. General conceptual model for the effects of tobacco control regulations



Content of the ITC Surveys

Surveillance content

Mixed Surveillance and policy content

**Unique ITC Content:
150+ Qs
focusing on
policy impact**

Surveillance content

| Content Domain | Number of Qs |
|---|--------------|
| Smoking History and Frequency → – Age started, 100 cigs, | 7 |
| Smoking Behaviour (current) and Dependence → – Cigs/day, time to first, perceived addiction | 7 |
| Quitting: ever tried, most recent attempt → – Duration of last attempt, planning vs. spontaneous, | 6 |
| Quitting: Beliefs, efficacy, intentions, motivation, reasons for → – Perceived role of policies | 21 |
| Knowledge: health effects, constituents → – Health conditions (e.g., lung cancer, stroke, impotence), role of nicotine | 22 |
| Health Warnings → – Noticing, thinking about health risks, motivate quitting, emotional reaction | 13 |
| Anti-smoking campaigns → – Noticing in various channels, perceived impact | 14 |
| Cigarette brand → – Choice, history, perceptions, last purchase: size, price paid | 35 |
| Light/Mild and other supposedly reduced harm products → – Perceptions of brand, relative risk | 7 |
| Cessation assistance → – Physician mention, type of assistance sought, effectiveness | 19 |
| ETS and Smoke-Free policies → – Personal policies (home, car), restaurants, bars, workplace (prevalence/support) | 53 |
| Psychosocial beliefs about smoking (mediators) and moderators | 27 |
| Advertising/Promotion | 25 |
| Tobacco industry beliefs and government role in TC beliefs → – Trust in industry, need for regulation, should govt do more? | 8 |
| Individual difference variables → – Depression, time perspective, rebelliousness | 18 |
| Demographics → – Age, marital status (also whether partner smokes), income, education | 13 |
| TOTAL NUMBER OF QUESTIONS (MAXIMUM) | 272 |

Throughout the policy sections there are measures relevant to monitoring

ITC China Supplement in *Tobacco Control* (Oct 2010)

October 2010 Volume 19 Supplement 2

TOBACCO CONTROL

Identifying the challenges to tobacco control in China

Special Tobacco Control supplement



Findings from the International Tobacco Control (ITC) China Project

Guest Editor: Simon Chapman



tobaccocontrol.bmj.com

BMJ Journals

October 2010 Volume 19 Supplement 2

TOBACCO CONTROL

明确烟草控制在中国面临的挑战

烟草控制特别增刊



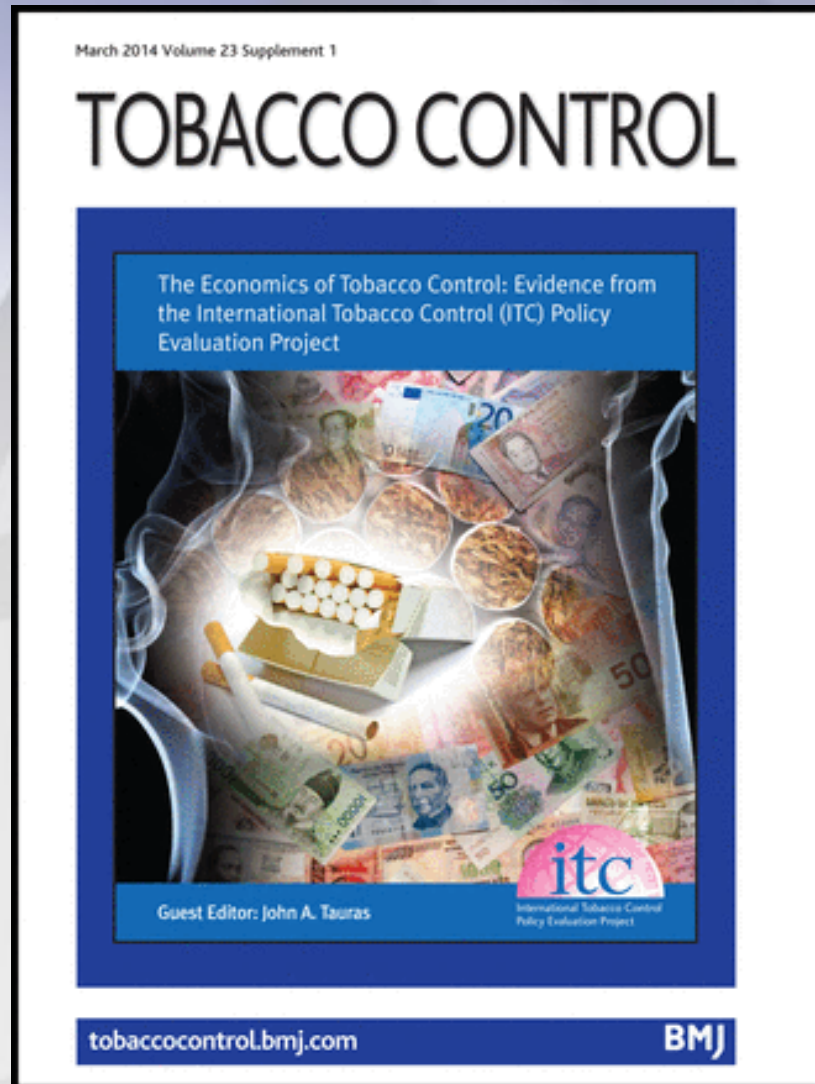
国际烟草控制政策评估研究 (ITC) 中国调查结果



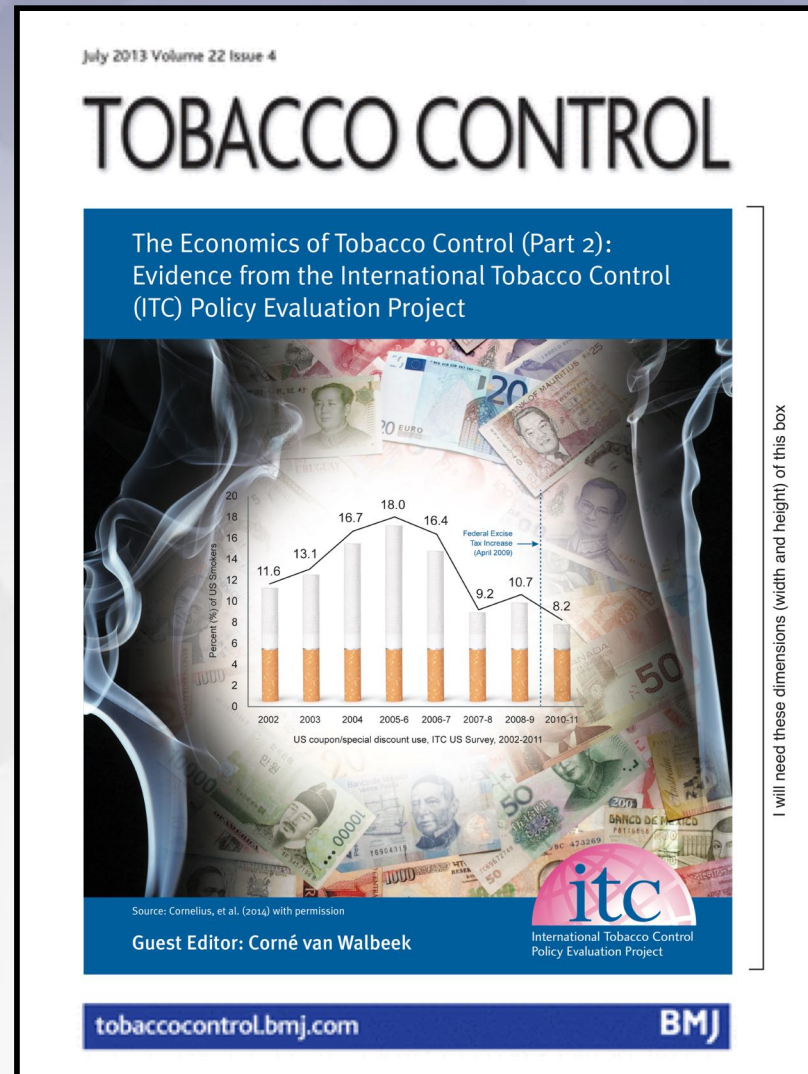
tobaccocontrol.bmj.com

BMJ Journals

ITC Economics Supplements

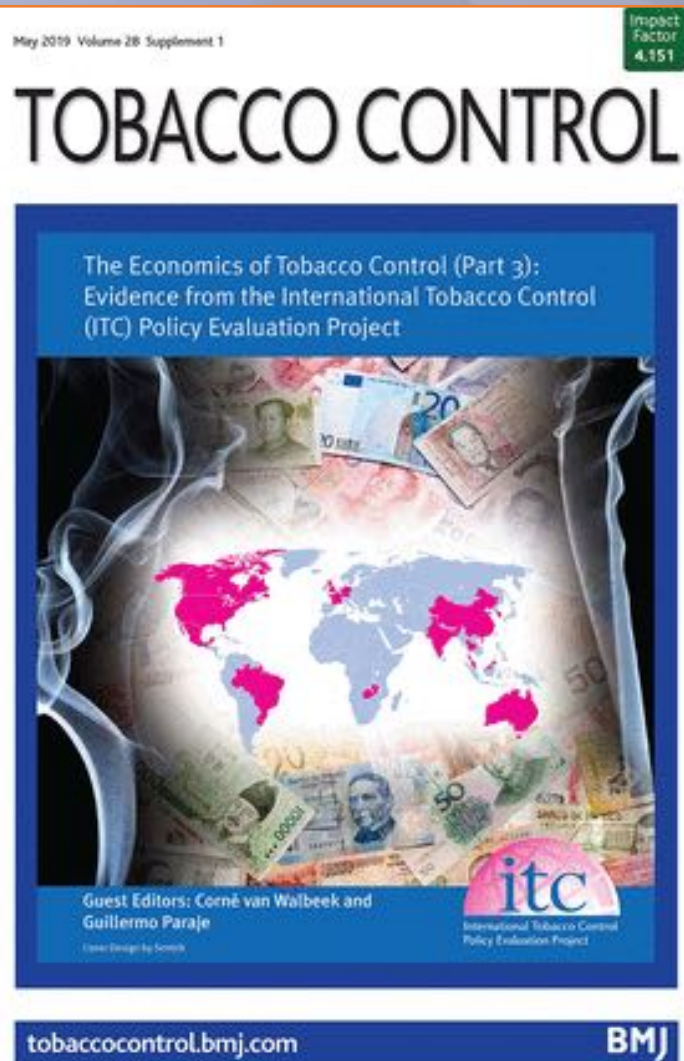


March 2014



July 2015

ITC Third Economics Supplement



Contents

Editorial

- s1** Economics of tobacco control (part 3): evidence from the ITC Project
C van Walbeek, G Paraje

Research papers

- s3** Association between tobacco prices and smoking onset: evidence from the TCP India Survey
C Shang, F J Chaloupka, P C Gupta, M S Pednekar, G T Fong
- s9** Individualised tobacco affordability in the UK 2002–2014: findings from the International Tobacco Control Policy Evaluation Project
T R Partos, J R Branstetter, R Hiscock, A B Gilmore, A McNeill
- s20** Trend in the affordability of tobacco products in Bangladesh: findings from the ITC Bangladesh Surveys
N Nargis, M Stoklosa, J Drope, G T Fong, A C K Quah, P Driezen, C Shang, F J Chaloupka, A K M G Hussain
- s31** Association between tax structure and cigarette consumption: findings from the International Tobacco Control Policy Evaluation (ITC) Project
C Shang, H M Lee, F J Chaloupka, G T Fong, M Thompson, R J O'Connor
- s37** The Impact of Income and Taxation in a Price-Tiered Cigarette Market: findings from the ITC Bangladesh Surveys
I Huq, N Nargis, D Lkhagvasuren, A K M G Hussain, G T Fong
- s45** Price, tax and tobacco product substitution in Zambia: findings from the ITC Zambia Surveys
M Stoklosa, F Goma, N Nargis, J Drope, G Chelwa, Z Chisha, G T Fong
- s53** Tobacco taxation, illegal cigarette supply and geography: findings from the ITC Uruguay Surveys
D Curti, C Shang, F J Chaloupka, G T Fong
- s61** Does free or lower cost smoking cessation medication stimulate quitting? Findings from the International Tobacco Control (ITC) Netherlands and UK Surveys
F A van den Brand, G E Nagelhout, K Hummel, M C Willemsen, A McNeill, O C P van Schayck
- s68** Impact of China National Tobacco Company's 'Premiumization' Strategy: longitudinal findings from the ITC China Surveys (2006–2015)
S S Xu, S Gravely, G Meng, T Elton-Marshall, R J O'Connor, A C K Quah, G Feng, Y Jiang, G J Hu, G T Fong

PostScript

- s77** Acknowledgement

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



International Tobacco Control
Policy Evaluation Project

Evaluating FCTC Policies: Graphic Health Warnings

Graphic Warnings in the US: Second attempt

FDA Proposes New Health Warnings for Cigarette Packs and Ads

Using new text statements and color images, the agency is poised to fill gaps in the public's understanding of cigarette smoking's negative health consequences.

[f Share](#)

[t Tweet](#)

[in LinkedIn](#)

[✉ Email](#)

[🖨 Print](#)



WARNING:

Smoking causes head and neck cancer.



WARNING:

Tobacco smoke causes fatal lung disease in nonsmokers.



WARNING:

Smoking causes cataracts, which can lead to blindness.



WARNING:

Smoking reduces blood flow, which can cause erectile dysfunction.



WARNING:

Tobacco smoke can harm your children.



WARNING:

Smoking causes bladder cancer, which can lead to bloody urine.



WARNING:

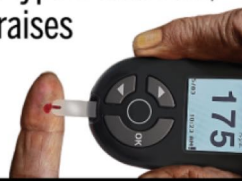
Smoking reduces blood flow to the limbs, which can require amputation.



WARNING: Smoking causes COPD, a lung disease that can be fatal.



WARNING: Smoking causes type 2 diabetes, which raises blood sugar.



WARNING:

Smoking during pregnancy stunts fetal growth.



WARNING:

Smoking can cause heart disease and strokes by clogging arteries.



WARNING:

Tobacco
smoke can
harm your
children.

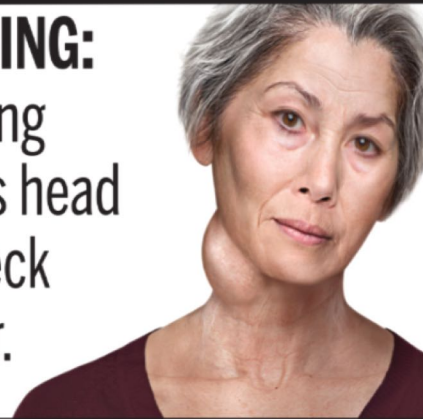



BRAND
FILTER CIGARETTES

20 CLASS A CIGARETTES

WARNING:

Smoking
causes head
and neck
cancer.



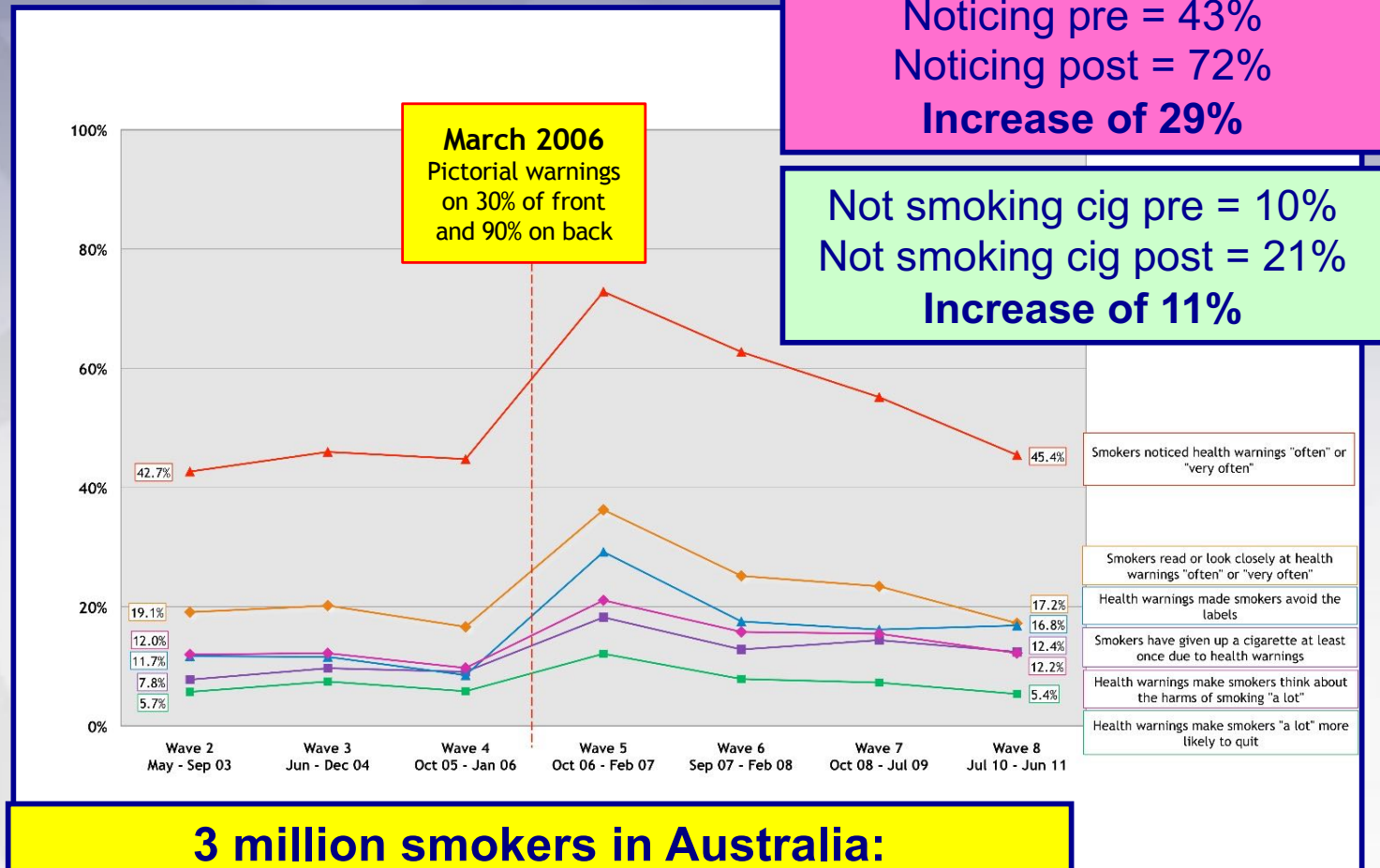

BRAND
FILTER CIGARETTES

20 CLASS A CIGARETTES

Measures of Effectiveness for Health Warnings

| WHO FCTC Article 11 Guidelines | Current | Proposed |
|------------------------------------|---------|----------|
| Large, clear, visible, and legible | X | ✓ |
| Includes full color pictures | X | ✓ |
| Covers at least 50% of pack | X | ✓ |
| Top of pack | X | ✓ |
| Front and back of pack | X | ✓ |
| Country's principal language | ✓ | ✓ |
| Rotated periodically | X | ✓ |
| Provides advice about cessation | X | X |
| Ban on misleading descriptors | X | ✓ |

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



3 million smokers in Australia:

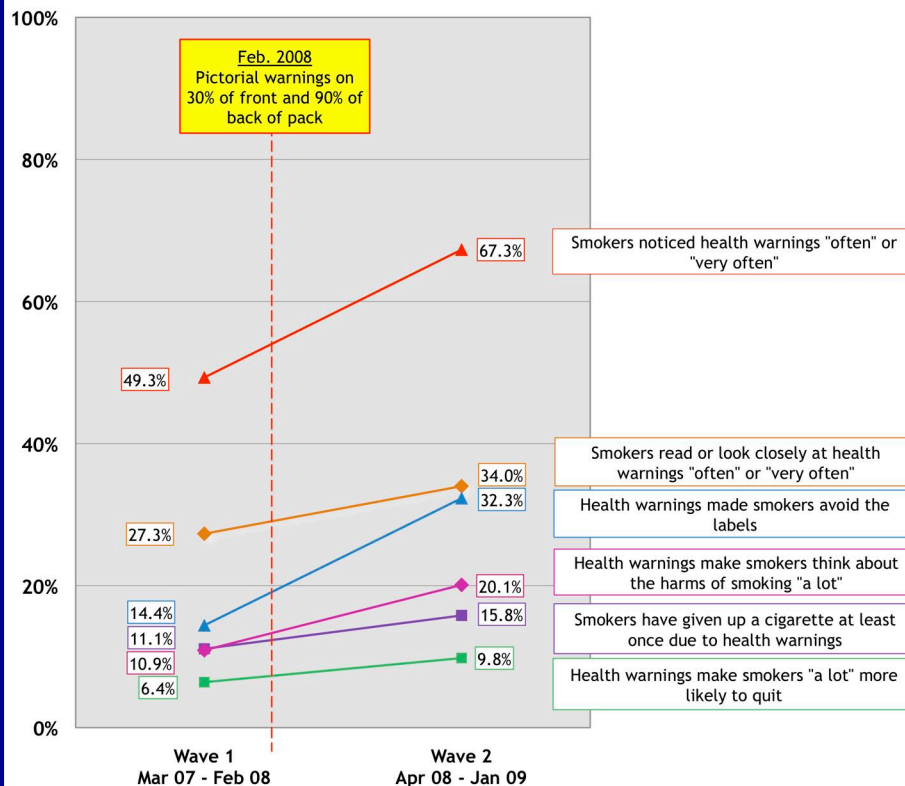
After the introduction of pictorial warnings:

- 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

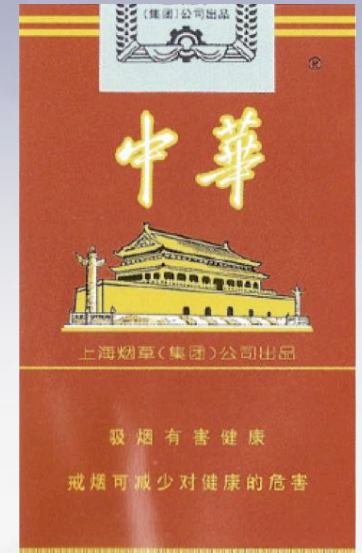
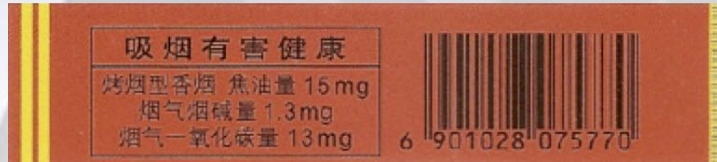
The lower effectiveness of text-only health warnings in China compared to pictorial health warnings in Malaysia

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...

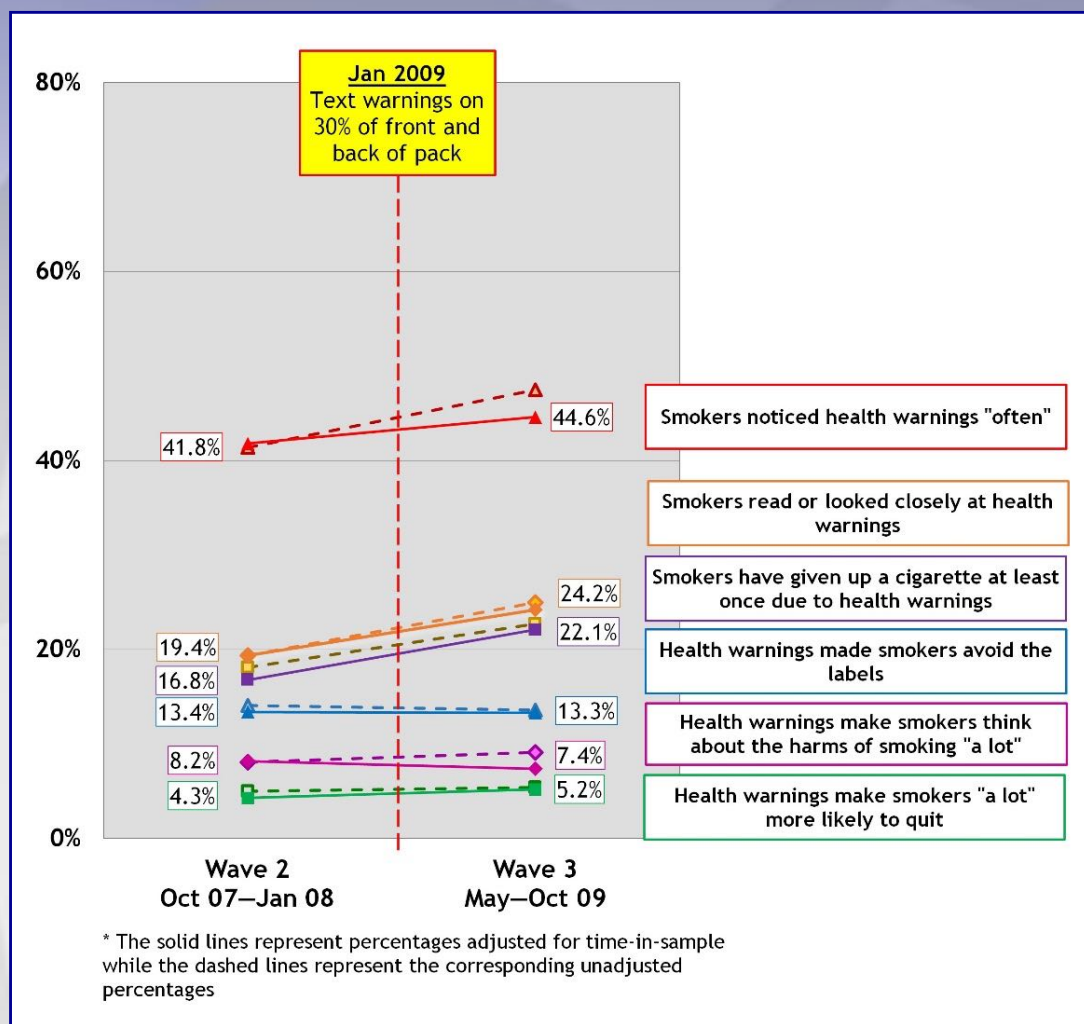
**2009
China stayed text-only**



**2009
Malaysia went to graphic**



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



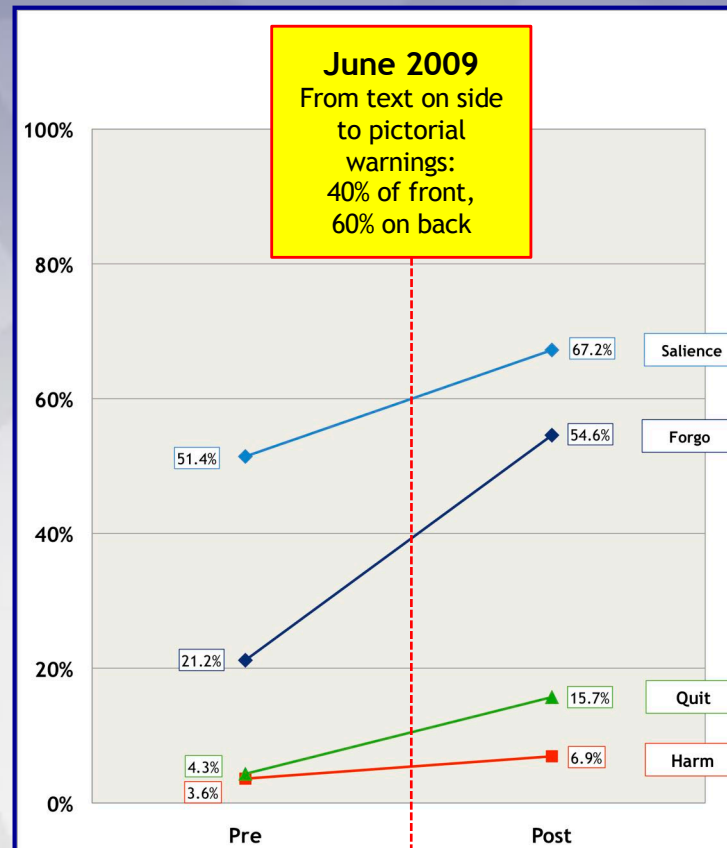
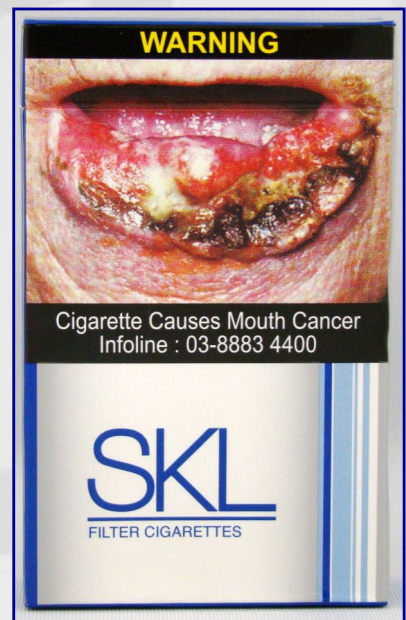
Noticing pre = 41.8%
Noticing post = 44.6%
Increase of 2.8%

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)

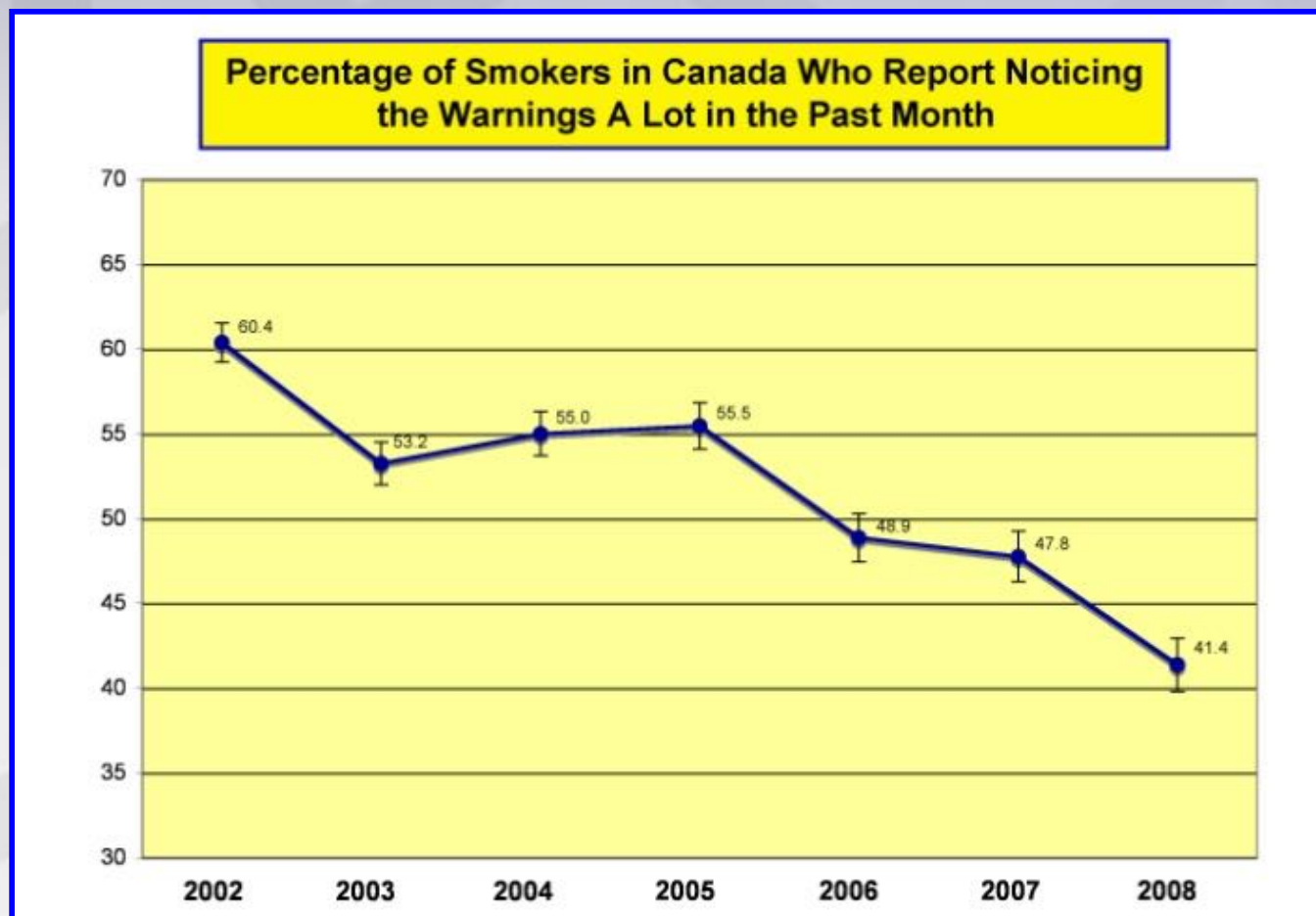


China Report released in Beijing in Dec 2012 at the Chinese Communist Party School and at the China NCD Forum



Before the 2012 Revision: significant wear-out

ITC Canada Survey: From 2002 to 2008, every indicator of label impact declined



Warning label wear-out

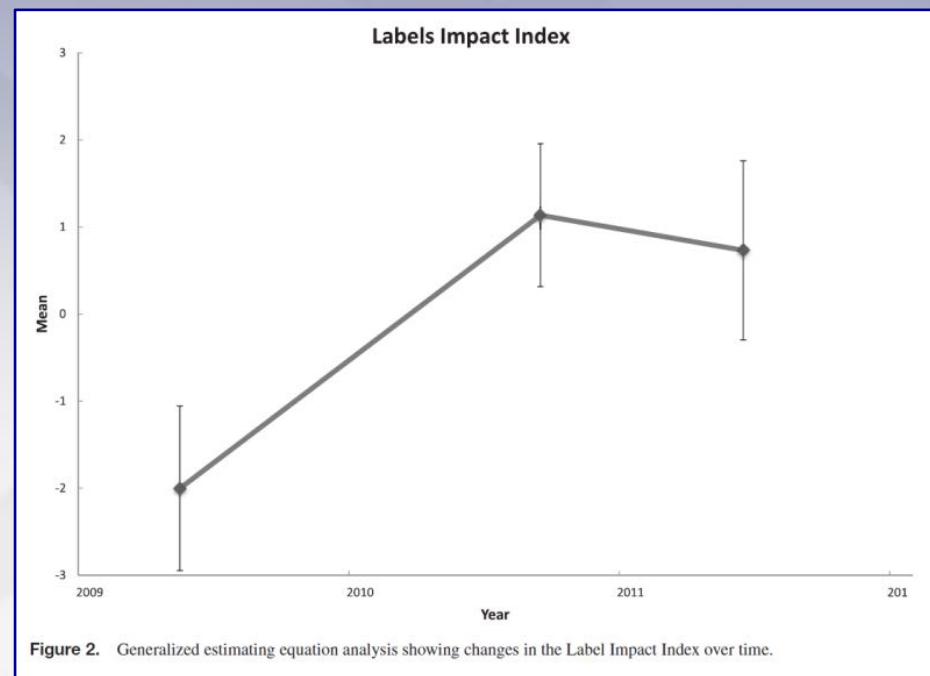
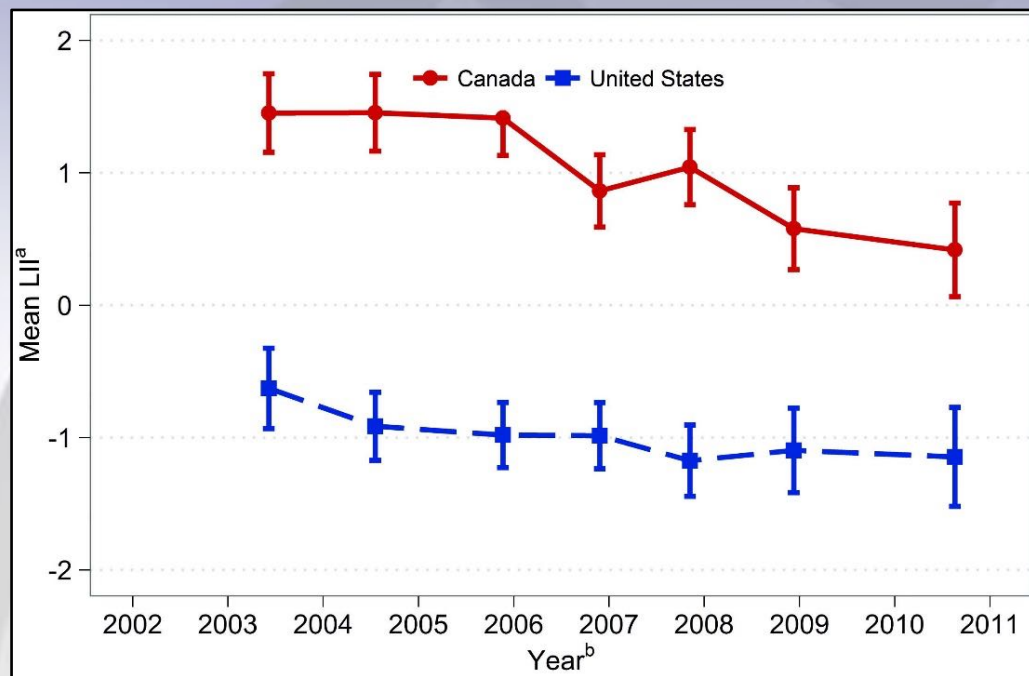


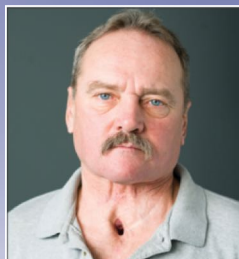
Figure 2. Generalized estimating equation analysis showing changes in the Label Impact Index over time.

Canada and US (2003-2011)

Mauritius (2009-2011)

Hitchman et al. 2014; Green et al. 2014

2012 Canadian warnings



"I wish I had never started smoking."

"I was diagnosed with cancer of the larynx when I was 48. I had to have my vocal cords removed, and now I breathe through a hole in my throat."
- Leroy

Need help to quit?
1-866-366-3667
gosmokefree.gc.ca/quit

Health Canada



"Just breathing is torture."

"Smoking caused my lungs to collapse four times before I was diagnosed with emphysema at 42. Without my oxygen tank, it feels like I'm breathing through a straw."
- Lena

Need help to quit?
1-866-366-3667
gosmokefree.gc.ca/quit

Health Canada



WARNING

Smoking in the car hurts more than just you.

Having the windows open does not protect passengers from the over 70 cancer causing chemicals in tobacco smoke.

You have the will. There is a way.
1-866-366-3667
gosmokefree.gc.ca/quit

Health Canada



WARNING

Cigarettes are a major cause of heart disease.

Smokers are up to 4 times more likely to develop heart disease than non-smokers.

You can quit. We can help.
1-866-366-3667
gosmokefree.gc.ca/quit

Health Canada



WARNING

Tobacco smoke hurts everyone.

Infants who are exposed to tobacco smoke are at greater risk of dying from Sudden Infant Death Syndrome (SIDS).

Need help to quit?
1-866-366-3667
gosmokefree.gc.ca/quit

Health Canada



WARNING

RISK OF BLINDNESS

Smoking may increase your risk of age-related macular degeneration, a condition that can cause permanent vision loss. There is no effective treatment in most cases.

Need help to quit?
1-866-366-3667
gosmokefree.gc.ca/quit

Health Canada



WARNING

ORAL CANCER

These white spots are a form of oral cancer caused primarily by smoking. Even if you survive, you may lose part or all of your tongue.

Need help to quit?
1-866-366-3667
gosmokefree.gc.ca/quit

Health Canada



"Look at the power of the cigarette... Remember this face and that smoking killed me."

Barb Tarbox died at 42 of lung cancer caused by cigarettes.

You can quit. We can help.
1-866-366-3667
gosmokefree.gc.ca/quit

Health Canada



WARNING

This is what dying of lung cancer looks like.

Barb Tarbox died at 42 of lung cancer caused by cigarettes.

You can quit. We can help.
1-866-366-3667
gosmokefree.gc.ca/quit

Health Canada




WARNING

A single stroke can leave you helpless.

Cigarettes are a major cause of stroke.

You can quit. We can help.
1-866-366-3667
gosmokefree.gc.ca/quit

Health Canada



WARNING

Another premature death...

Smoking is the leading preventable cause of premature death in Canada. About 100 people die from tobacco use each day.

You can quit. We can help.
1-866-366-3667
gosmokefree.gc.ca/quit

Health Canada



WARNING

Cigarettes cause bladder cancer.

Toxic chemicals in tobacco smoke damage the lining of the bladder causing cancer. The most common sign is blood in the urine.

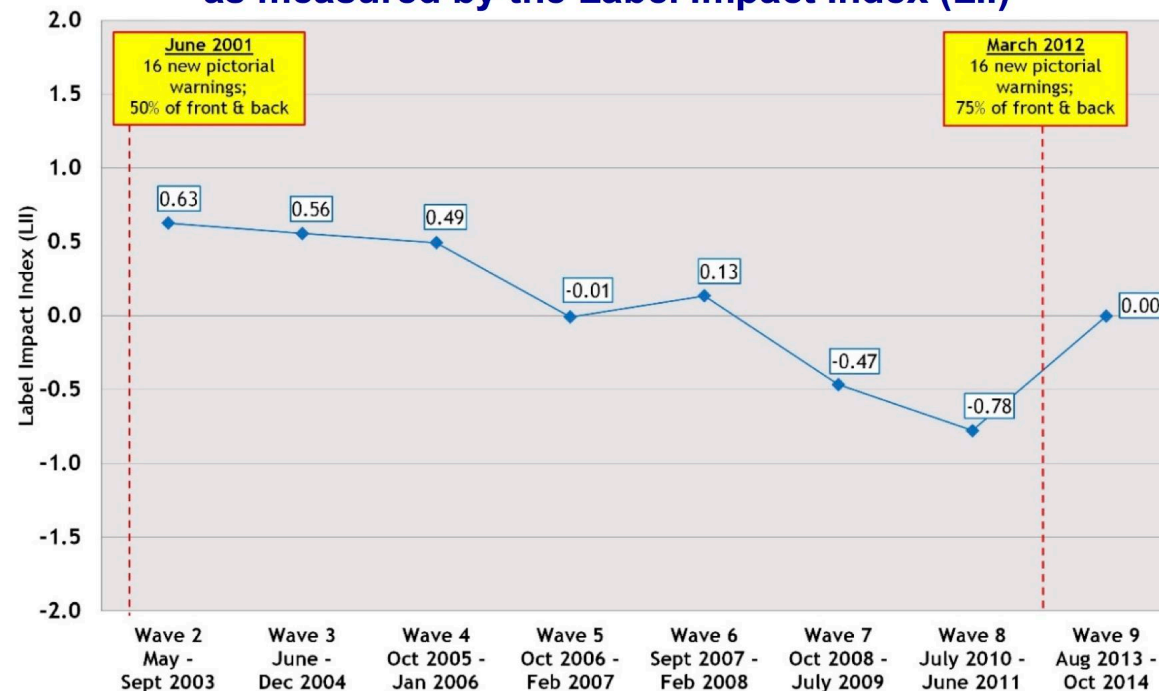
You have the will. There is a way.
1-866-366-3667
gosmokefree.gc.ca/quit

Health Canada

Impact of 2012 revision of warnings

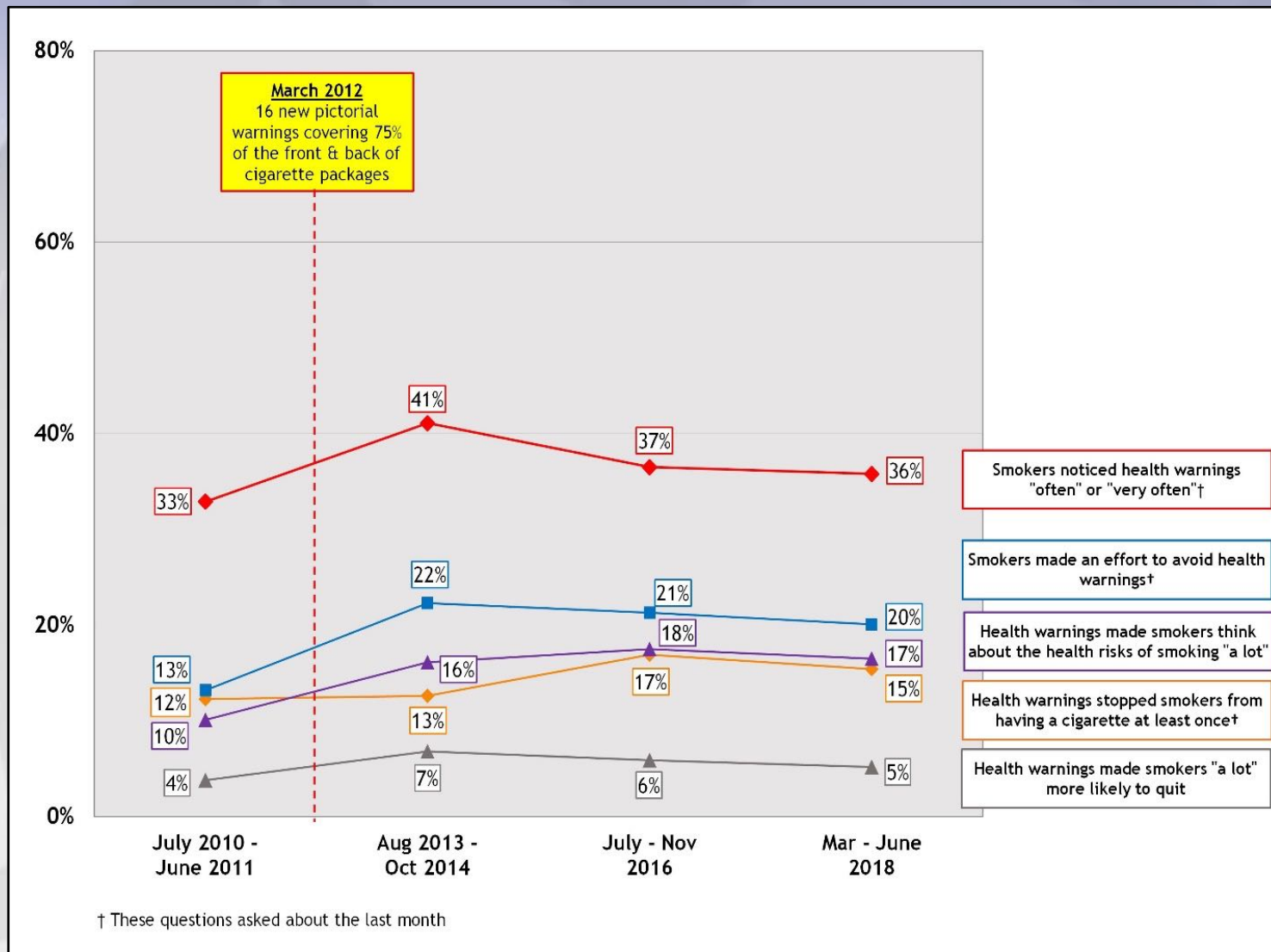
- ITC survey: Steady decline in warning impact from 2003-2011, but then a substantial increase with the 2012 revision.

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

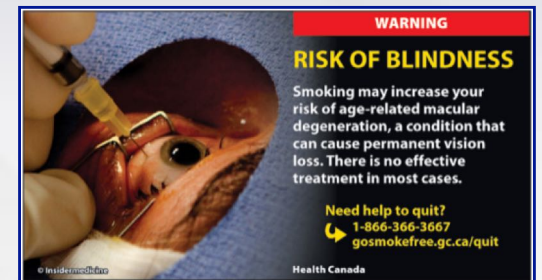
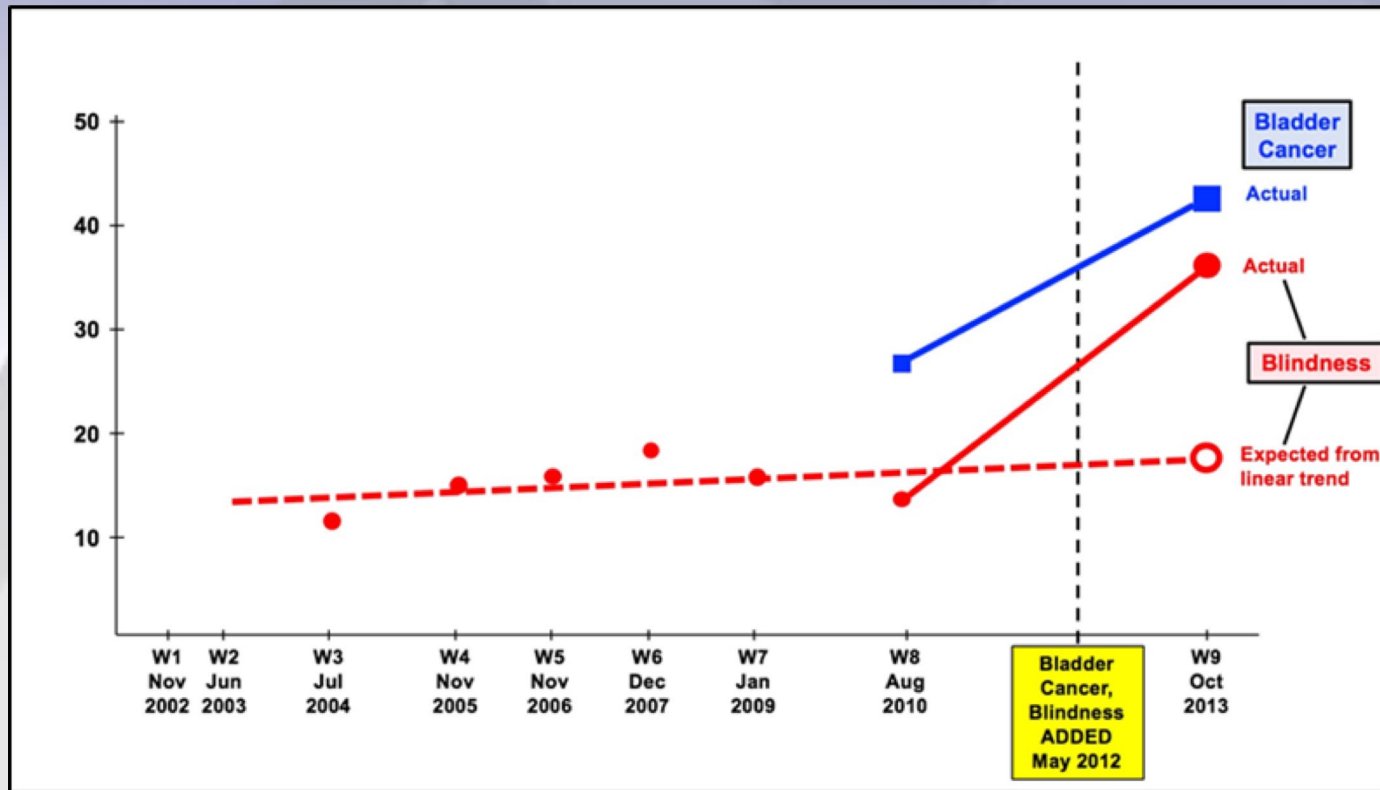


Note: Results are adjusted for age, sex, smoking status (daily/non-daily), and time-in-sample effects. The Label Impact Index (LII) was calculated by normalizing scores on four measures of warning label impact (noticing warnings, thinking about harms and thinking about quitting because of warnings, and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

The effects of the 2012 warnings on indicators of HW impact 2013 to 2018



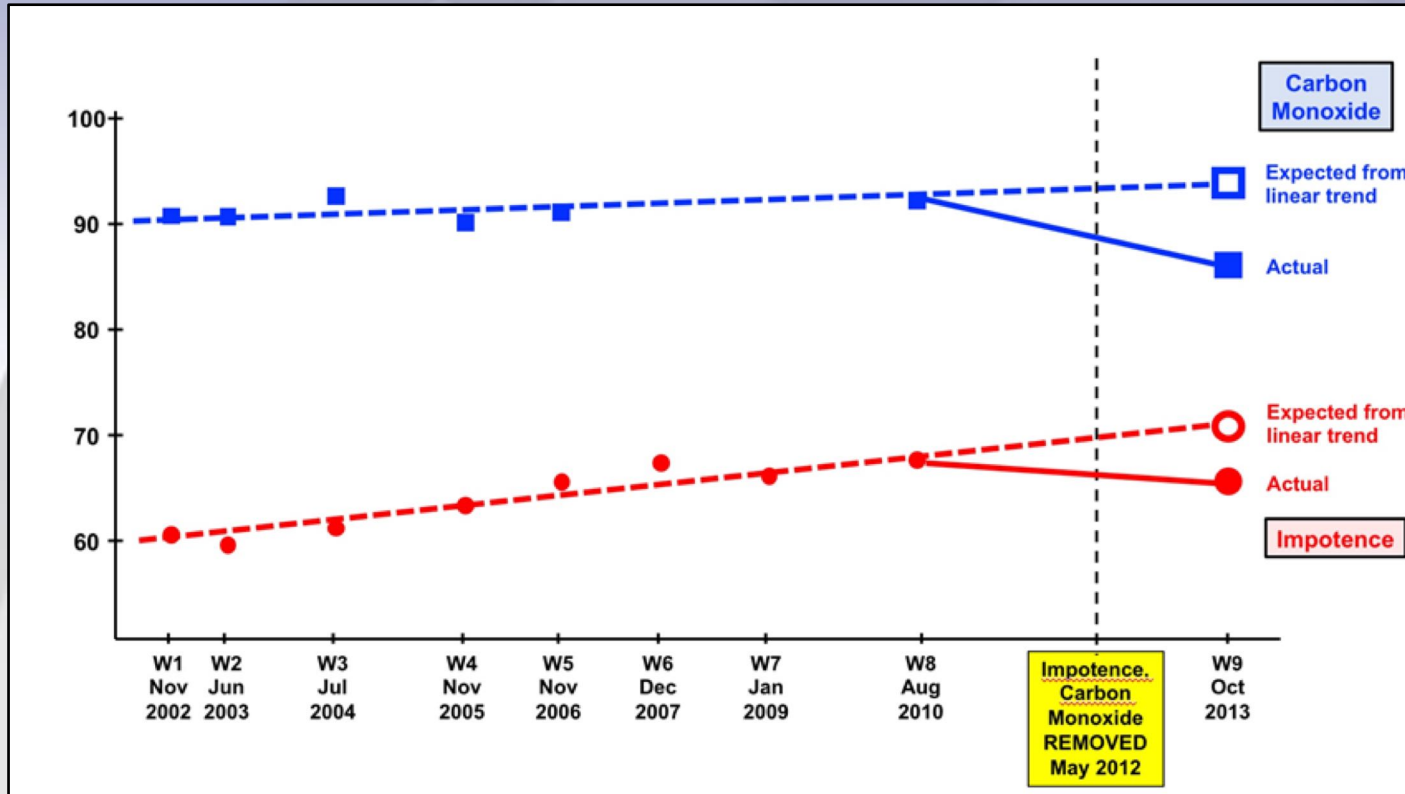
The effects of ADDING a health harm to the health warnings on knowledge/awareness



Green et al. *Tobacco Control* (2019)

Adding new health messages on effect of smoking on blindness and bladder cancer **increased awareness** of these health effects.

The effects of REMOVING a health harm to the health warnings on knowledge/awareness



Green et al. *Tobacco Control* (2019)

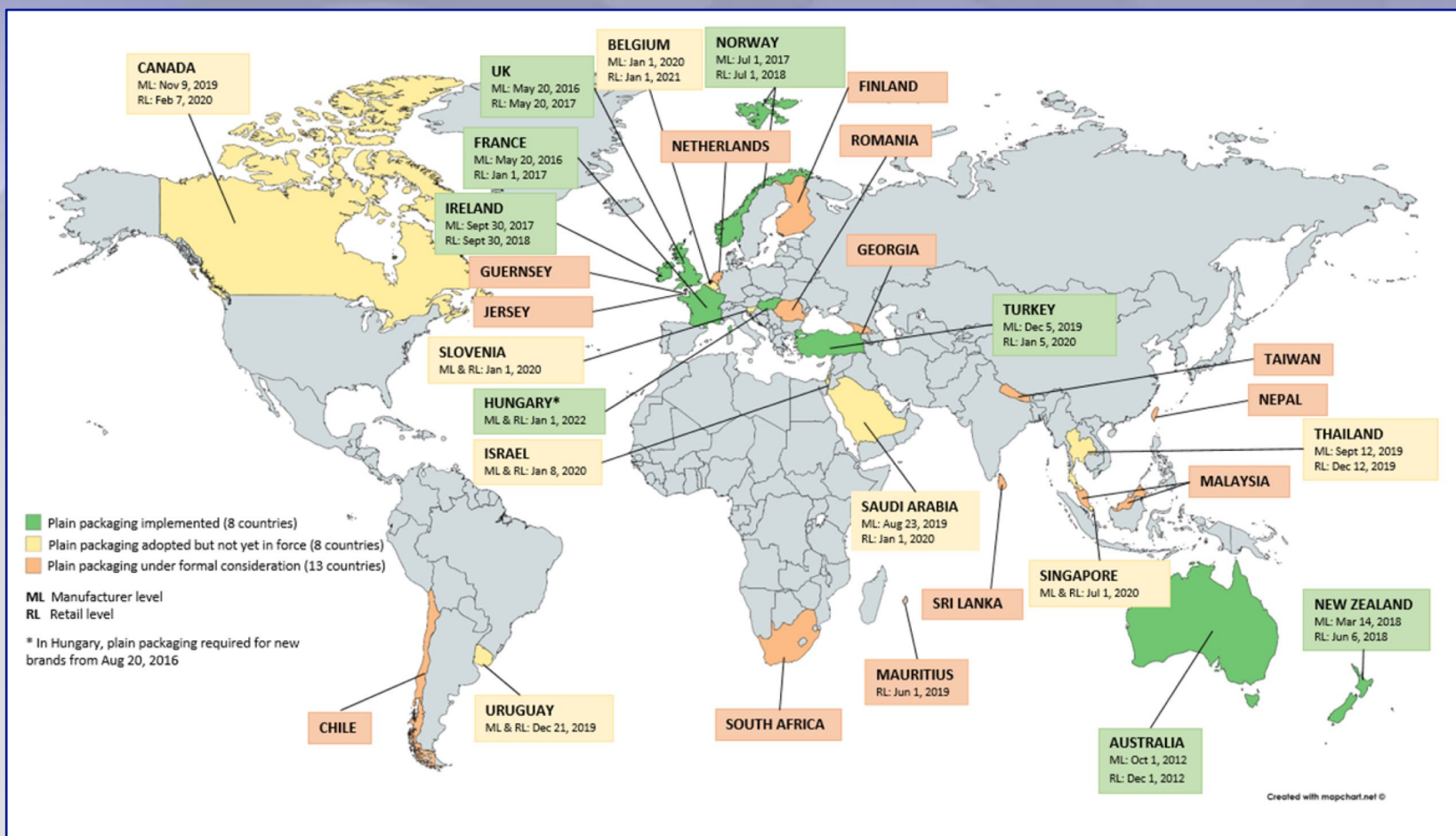
Removing impotence and carbon monoxide from the warnings **decreased awareness** of these health effects.



International Tobacco Control
Policy Evaluation Project

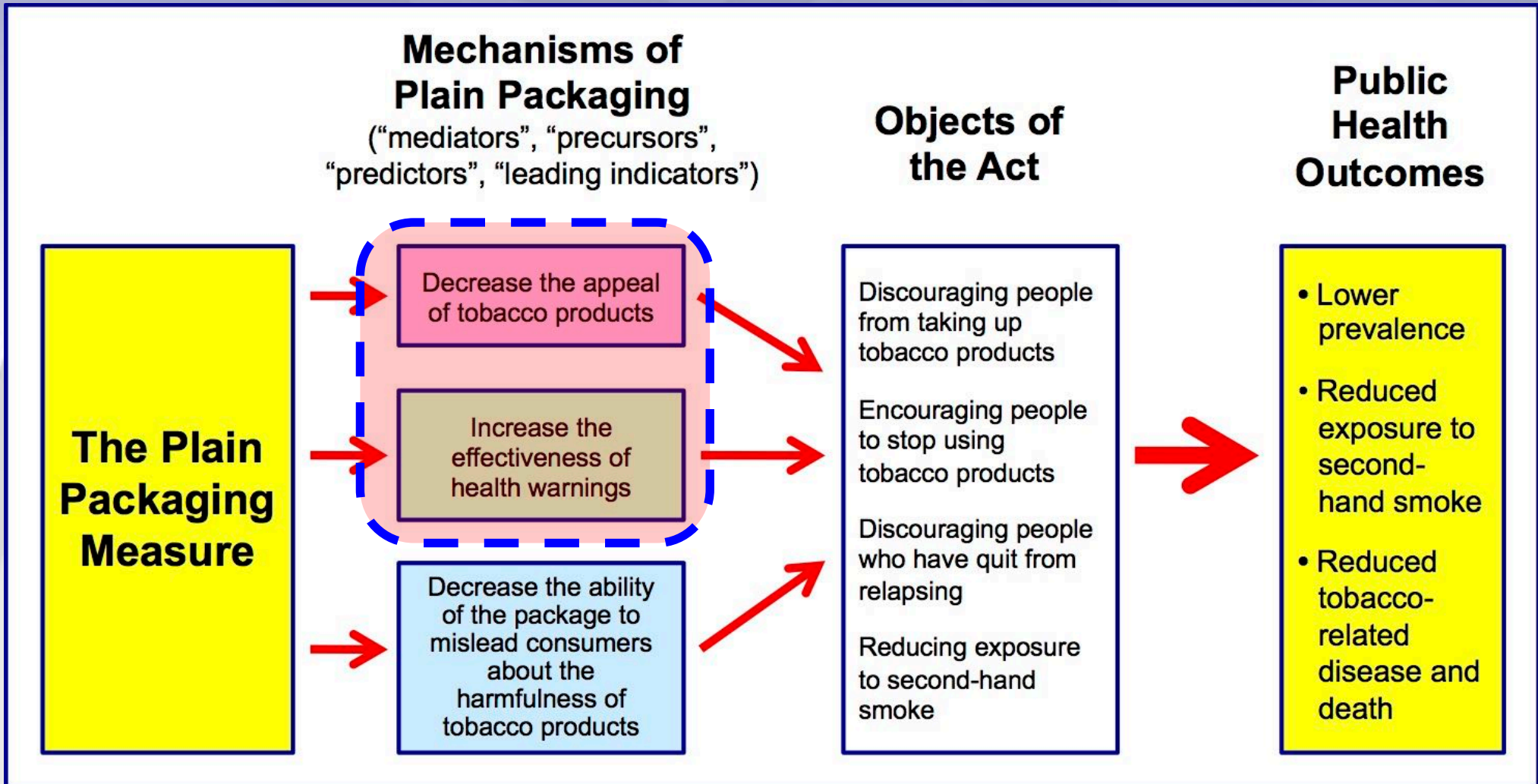
Evaluating Plain Packaging

Tobacco Plain Packaging—September 2019



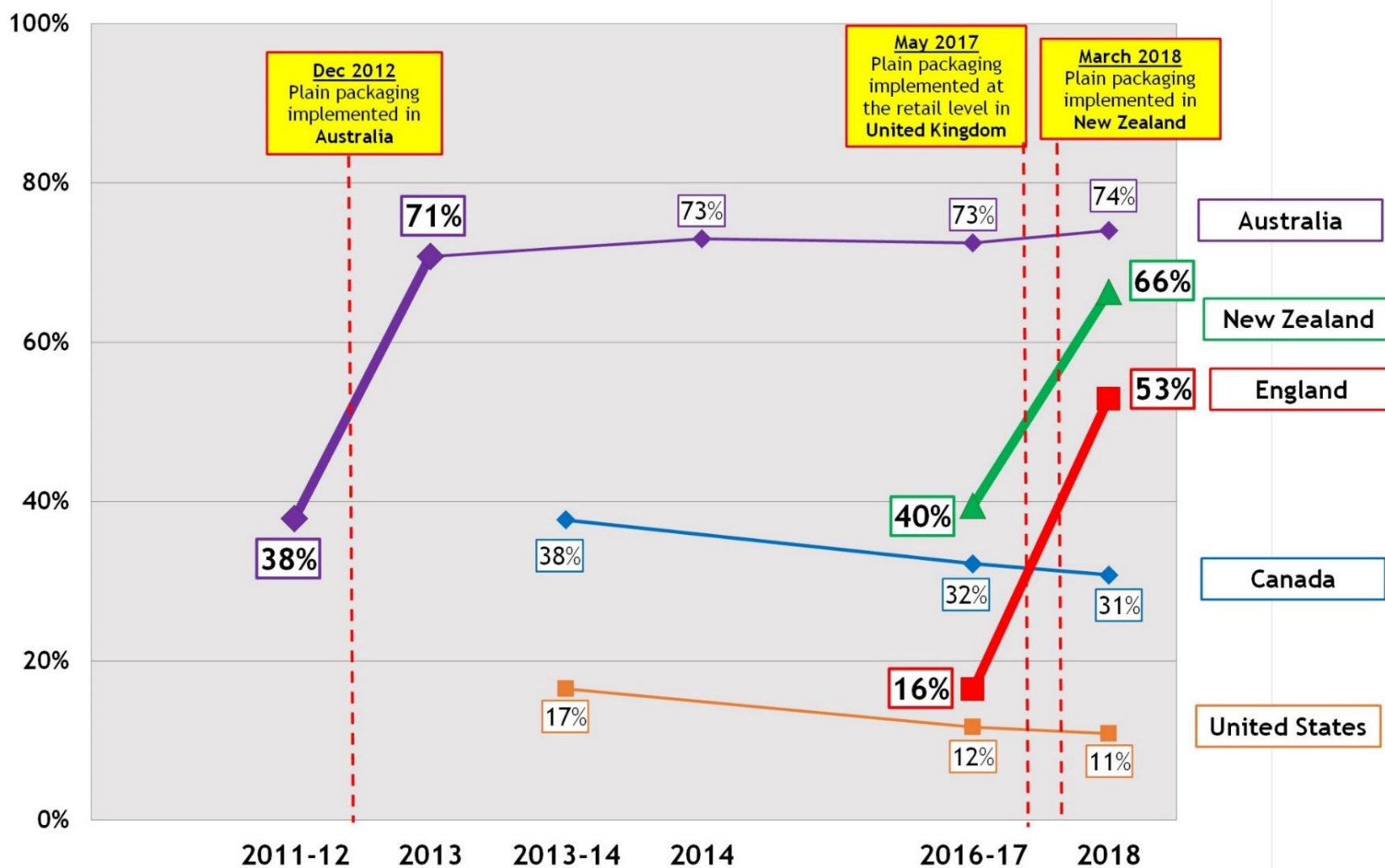
ITC Evaluation of Plain Packaging:
Australia, UK, New Zealand, France, Canada,
Uruguay, Mauritius, Netherlands

Tobacco Plain Packaging—Mediational Model



Appeal of Packs

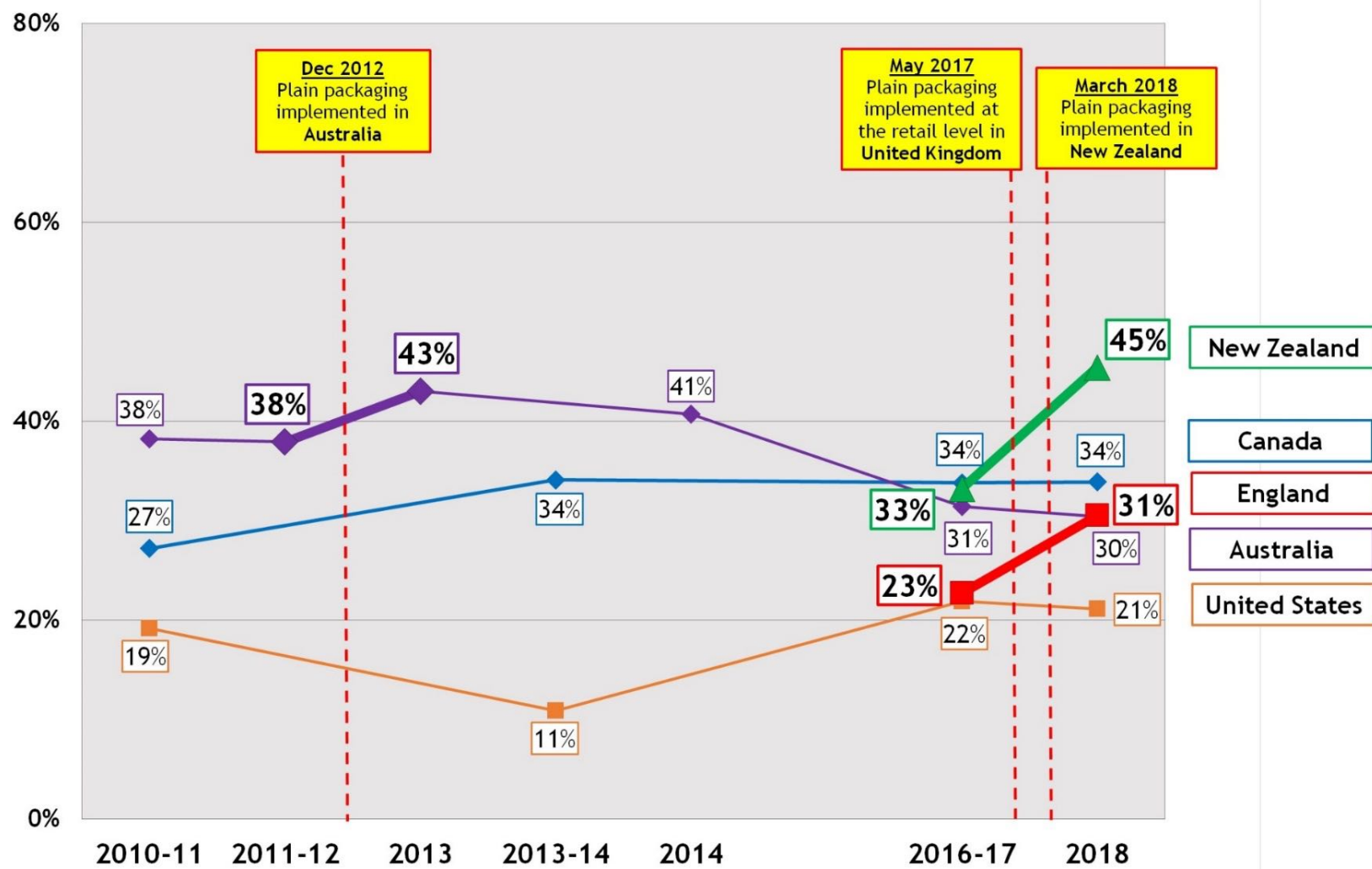
Percentage of smokers who don't like the look of their pack "at all", among those who have a regular brand of cigarettes, by ITC country and year



Note: results are aligned as close as possible to the years the survey was conducted in each country, with a couple of minor differences: 1) the survey years for the data point of 17% in the US were from 2013-15; 2) the New Zealand survey was done in 2016-17, but the corresponding data points for the other four countries were from 2016.

Noticed Warning Labels

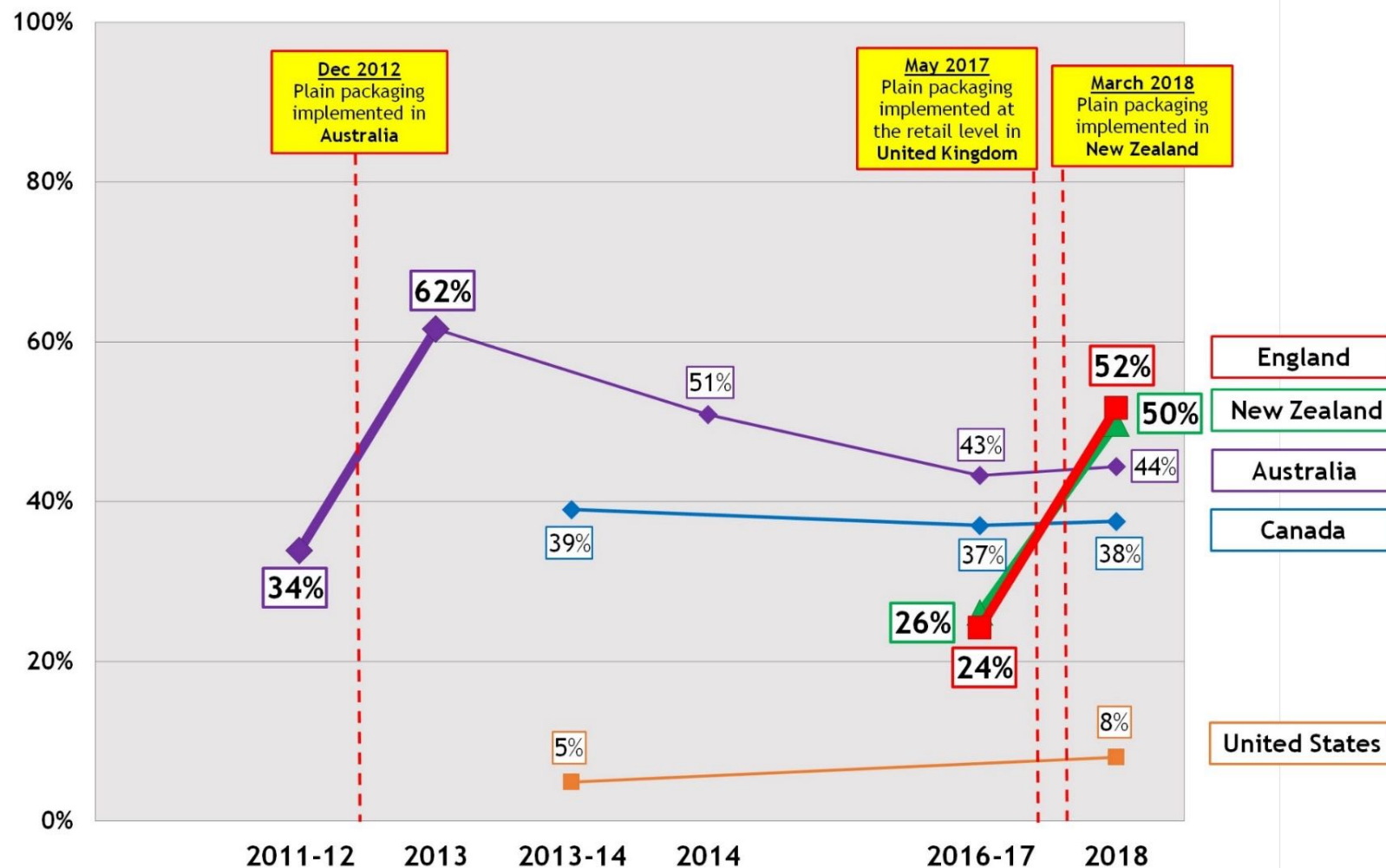
Percentage of smokers and quitters who noticed warning labels on cigarette packages "often" or "very often" in the last month, by ITC country and year



Note: results are aligned as close as possible to the years the survey was conducted in each country, with a couple of minor differences: 1) the survey years for the data point of 11% in the US were from 2013-15; 2) the New Zealand survey was done in 2016-17, but the corresponding data points for the other four countries were from 2016.

Noticed Warning Labels

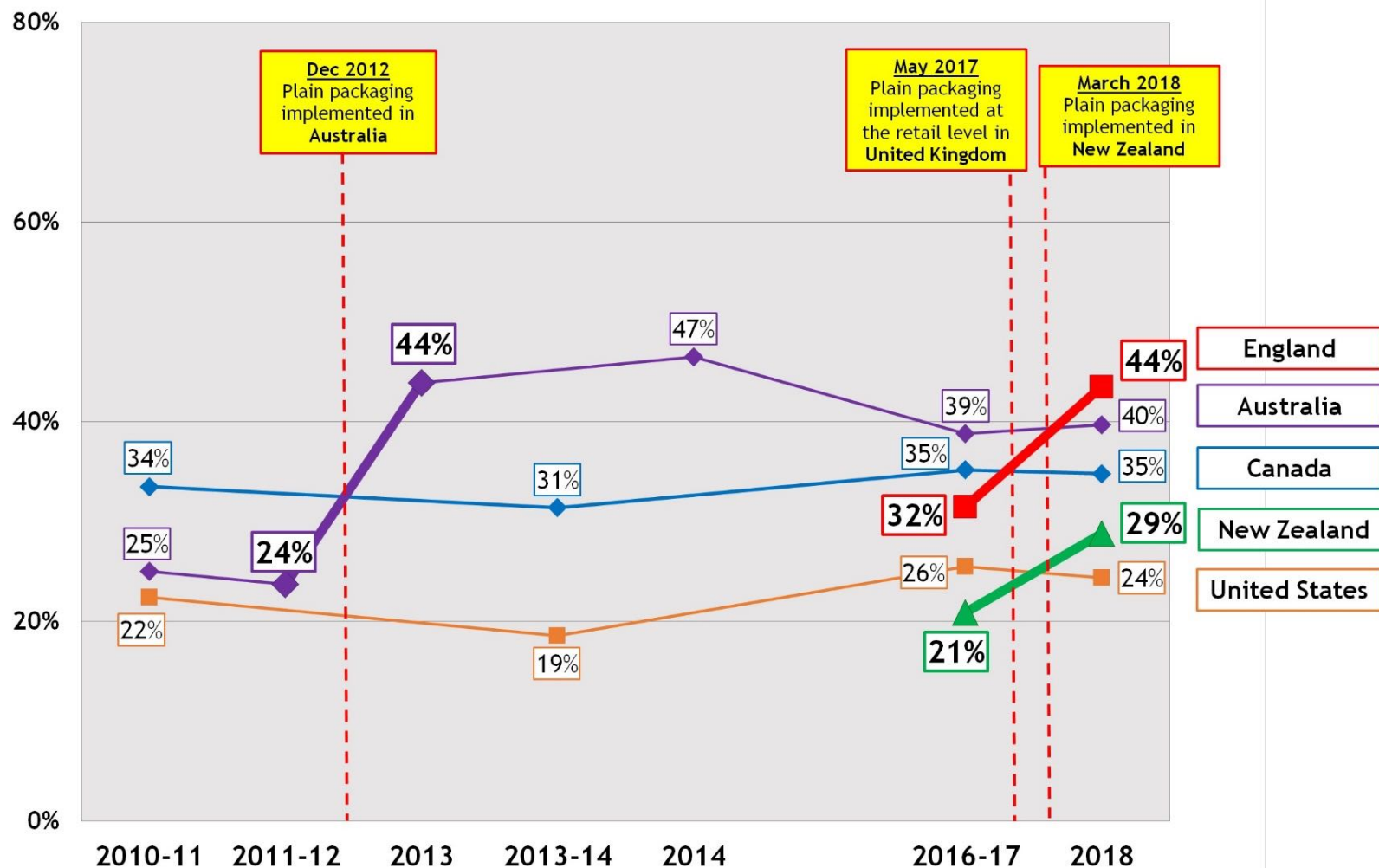
Percentage of smokers and quitters who said they notice warning labels first when they look at a cigarette pack (versus other aspects of the pack such as branding), by ITC country and year



Note: results are aligned as close as possible to the years the survey was conducted in each country, with a couple of minor differences: 1) the survey years for the data point of 5% in the US were from 2013-15; 2) the New Zealand survey was done in 2016-17, but the corresponding data points for the other four countries were from 2016. This question was not asked in the US in the 2016 survey.

Support for Plain Packaging

Percentage of smokers and quitters who "agree" or "strongly agree" that tobacco companies should be required to sell cigarettes in plain packages, by ITC country and year



Note: results are aligned as close as possible to the years the survey was conducted in each country, with a couple of minor differences: 1) the survey years for the data point of 19% in the US were from 2013-15; 2) the New Zealand survey was done in 2016-17, but the corresponding data points for the other four countries were from 2016.



International Tobacco Control
Policy Evaluation Project

Evaluating the impact of menthol cigarette bans on cessation and smoking behaviours in Canada: Findings from the 2016-18 ITC 4 Country Smoking and Vaping Surveys

Janet Chung-Hall¹, Geoffrey T. Fong^{1 2}, Gang Meng¹, Lorraine Craig¹,
Anne C.K. Quah¹, Janine Ouimet¹, and Steve Xu¹

US FDA recommendations for menthol ban

“Removal of menthol cigarettes from the marketplace would benefit public health in the United States.”

– Tobacco Products Scientific Advisory Committee
(TPSAC) report (2011)

“... menthol cigarettes pose a public health risk above that seen with nonmenthol cigarettes.”

– 2013 US FDA report

US FDA activity on menthol

Cigarettes:

- 2009 Family Smoking Prevention and Tobacco Control Act: prohibits use of flavors in cigarettes but exempts menthol
- Nov 2018: FDA Notice of Proposed Rulemaking to include provision for ban on menthol cigarettes
- June 2020: African American Tobacco Control Leadership Council and Action on Smoking and Health lawsuit against FDA

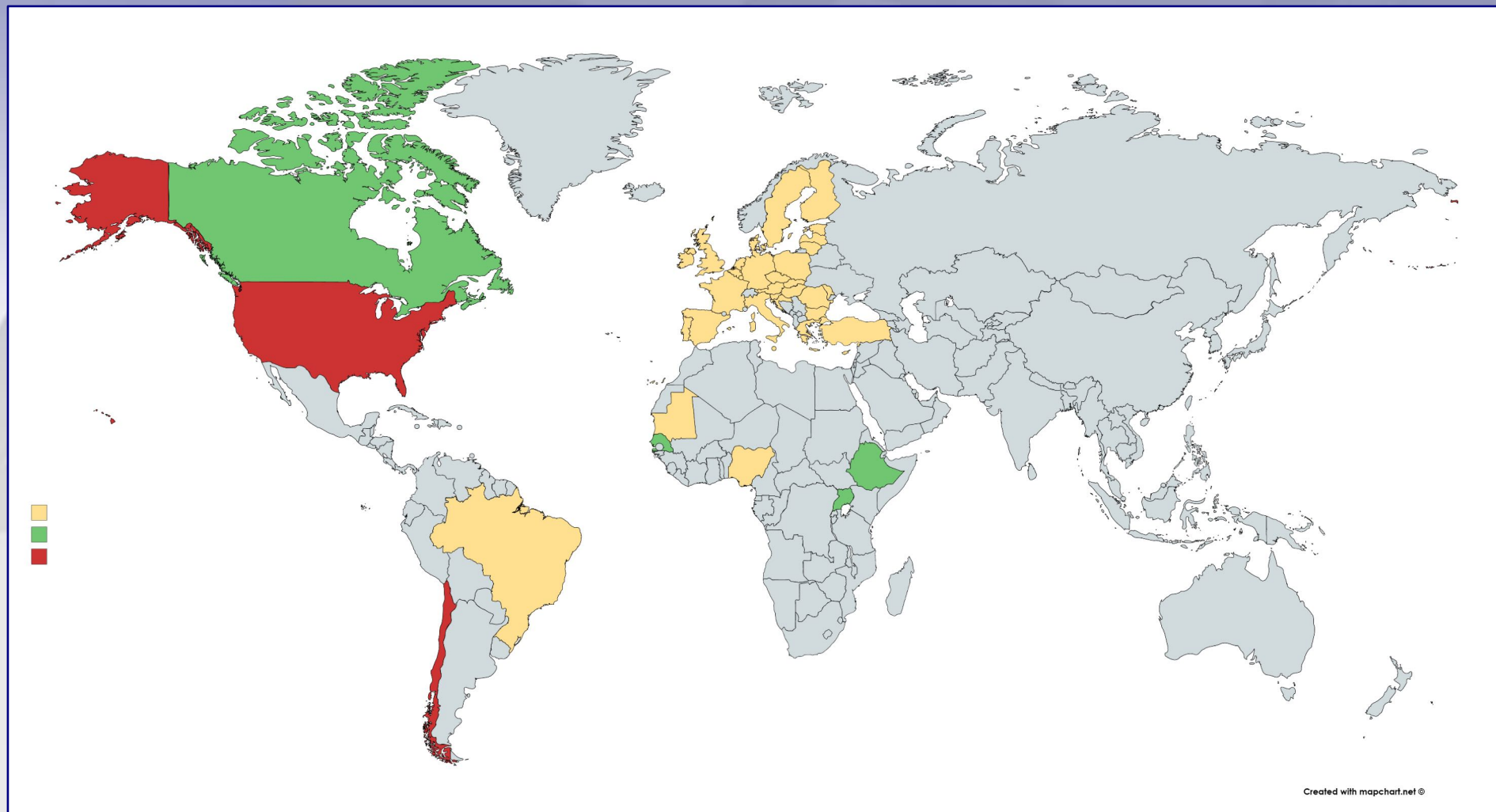
E-Cigarettes:

- Feb 6, 2020: implementation of federal ban on most flavors in one type of EC cartridge- or pod-based products (Juul)
- Exemptions for disposable flavored ECs, nicotine e-liquids currently available in +15,000 flavors, other refillable open systems, and menthol varieties of Juul and other cartridge/pod-based ECs
- Feb 28, 2020: bill that would ban all flavored tobacco products (i.e., ECs, menthol cigarettes, and flavored cigars) passed by US House of Representatives

Menthol cigarettes in Canada

- 5.4% of the Canadian cigarette market (2016)
- Higher rates of use for youth vs. adults (past 30 days)
 - **21%** of high school students smoked menthols (2012-13)
 - **2%** of adults smoked menthols (2015)
- Menthol flavour capsule products introduced in 2015
- Nova Scotia: first jurisdiction to ban menthol (May 2015)
- National menthol ban (October 2017)

National menthol bans: Global status



- Menthol ban implemented (4 countries)
- Menthol ban adopted but not yet in force (33 countries)
- Menthol ban under formal consideration (2 countries)

Pre-post evaluation of menthol ban in Ontario (Chaiton et al., 2019)

Research paper

Ban on menthol-flavoured tobacco products predicts cigarette cessation at 1 year: a population cohort study

Michael O Chaiton,^{1,2} Ioana Nicolau,^{1,2} Robert Schwartz,² Joanna E Cohen,³ Eric Soule,⁴ Bo Zhang,^{2,5} Thomas Eissenberg⁶

► Additional material is published online only. To view please visit the journal online (<http://dx.doi.org/10.1136/tobaccocontrol-2018-054841>).

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⁴Health Education and Promotion, East Carolina University, Greenville, North Carolina, USA

⁵Dalla Lana School of Public Health, University of Toronto, Toronto, Ontario, Canada

⁶Department of Psychology and Center for the Study of Tobacco Products, Virginia Commonwealth University, Richmond, Virginia, USA

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Received 13 November 2018

Revised 10 April 2019

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ABSTRACT

Objectives The province of Ontario, Canada, banned the use of menthol-flavoured tobacco products as of 1 January 2017. The long-term impact of a menthol ban on smoking behaviour has not been previously evaluated.

Methods Population cohort study with baseline survey conducted September–December 2016 and follow-up January–August 2018 among residents of Ontario, Canada, 16 years old and over who reported current smoking (past 30 days) at baseline survey and completed follow-up (n=913) including 187 reporting smoking menthol cigarettes daily, 420 reporting smoking menthol cigarettes occasionally, and 306 were non-menthol cigarette smokers. Relative rates of making a quit attempt and being a non-smoker at follow-up were estimated with Poisson regression controlling for smoking and demographic characteristics at baseline.

Results At follow-up, 63% of daily menthol smokers reported making a quit attempt since the ban compared with 62% of occasional menthol smokers and 43% of non-menthol smokers (adjusted relative rate (ARR) for daily menthol smokers compared with non-menthol smokers: 1.25; 95% CI 1.03 to 1.50). At follow-up, 24% of daily menthol smokers reported making a quit since the ban compared with 20% of occasional menthol smokers and 14% of non-menthol smokers (ARR for daily menthol smokers compared with non-menthol smokers: 1.62; 95% CI 1.08 to 2.42).

Conclusions The study found higher rates of quitting among daily and occasional menthol smokers in Ontario 1 year after the implementation of a menthol ban compared with non-menthol smokers. Our findings suggest that restrictions on menthol may lead to substantial improvements in public health.

INTRODUCTION

Menthol is a flavouring agent added to cigarettes that masks the taste of tobacco, induces sensory

The FDA noted in their scientific evaluation that menthol has a physiological impact on smoking that increases initiation and progression to regular cigarette smoking, increases nicotine dependence and decreases smoking cessation success.⁴ These findings were consistent across three independent reports (TPSAC report, FDA report and a 2017 systematic review by Villanti *et al.*).^{4,7} Further, the FDA report found that menthol smoking patterns differed by subpopulation.⁴ For instance, younger populations, women and black Americans were more likely to smoke menthol cigarettes.⁴ These menthol smoking patterns among subpopulations perfectly matched the targeted marketing strategies employed by the tobacco industry.⁴

Although there are strong recommendations for banning menthol tobacco products, very few countries have banned menthol cigarettes.^{8,9} Canada has implemented a new national ban to address rates of menthol cigarette use among youth.¹⁰ Other nations such as Brazil, Ethiopia, Turkey and the European Union have passed regulations to ban menthol tobacco products.^{8,9} In the USA, the FDA has announced intentions to regulate the sale of menthol in tobacco.¹¹ San Francisco has already banned the sale of menthol cigarettes and other tobacco products with flavours and many other local and state jurisdiction have or are considering implementing restrictions.^{12–14} Evaluating the impact of a menthol ban could inform the implementation of restrictions in other jurisdictions.

Several studies that have attempted to estimate the behavioural intentions following a menthol ban found that between 35% and 66% of current menthol smokers in the USA stated they would quit if there was a menthol ban.^{15–17} Further, a simulation study was conducted to predict the effects of a hypothetical menthol ban in the USA on smoking prevalence and smoking-attributable deaths.⁴⁰

Menthol ban effective for increasing quitting among menthol smokers vs. non-menthol smokers.

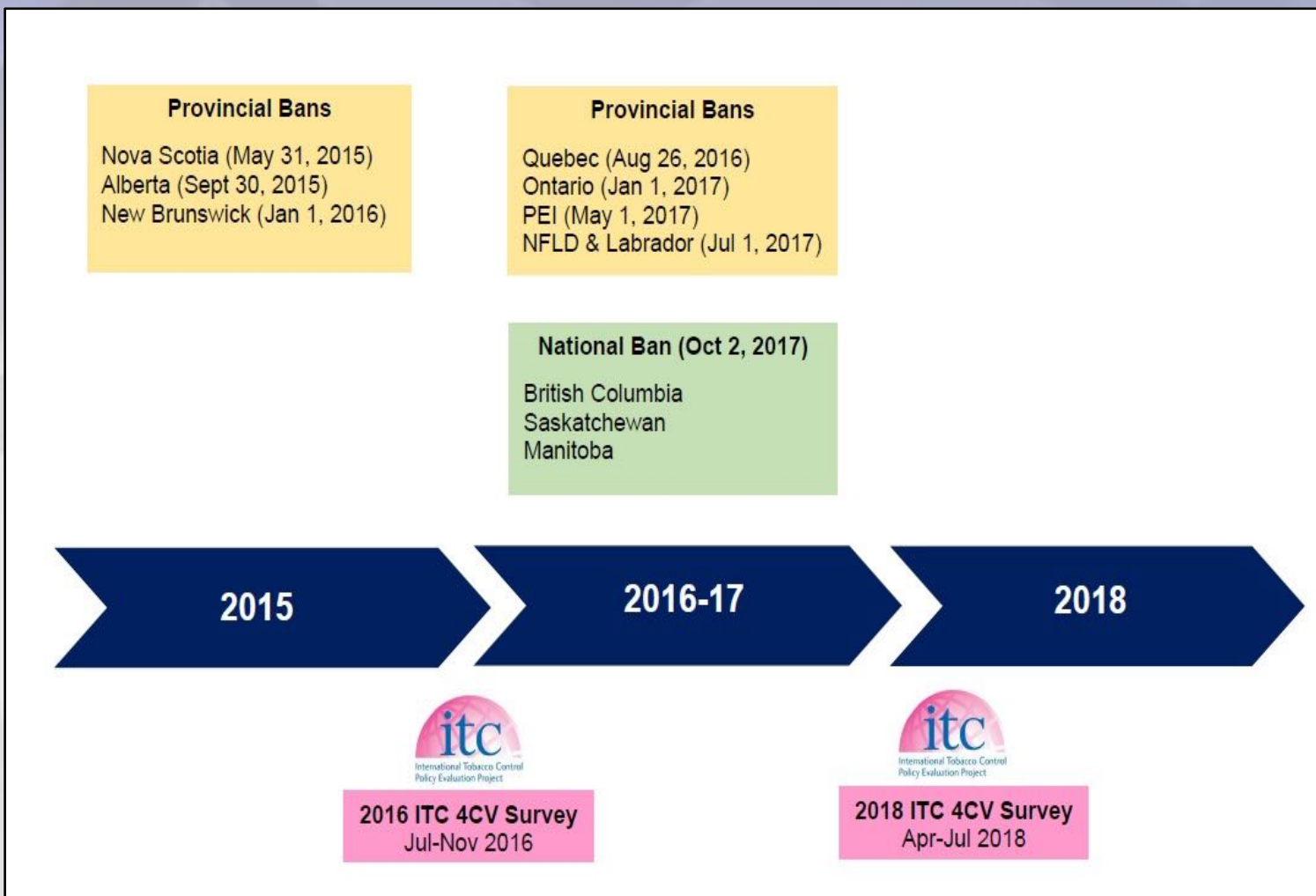
One year after menthol ban in Ontario:

- 63% menthol smokers made quit attempt vs. 43% non-menthol smokers (p<.001)
- 24% menthol smokers had quit vs. 14% non-menthol smokers (p<.05)

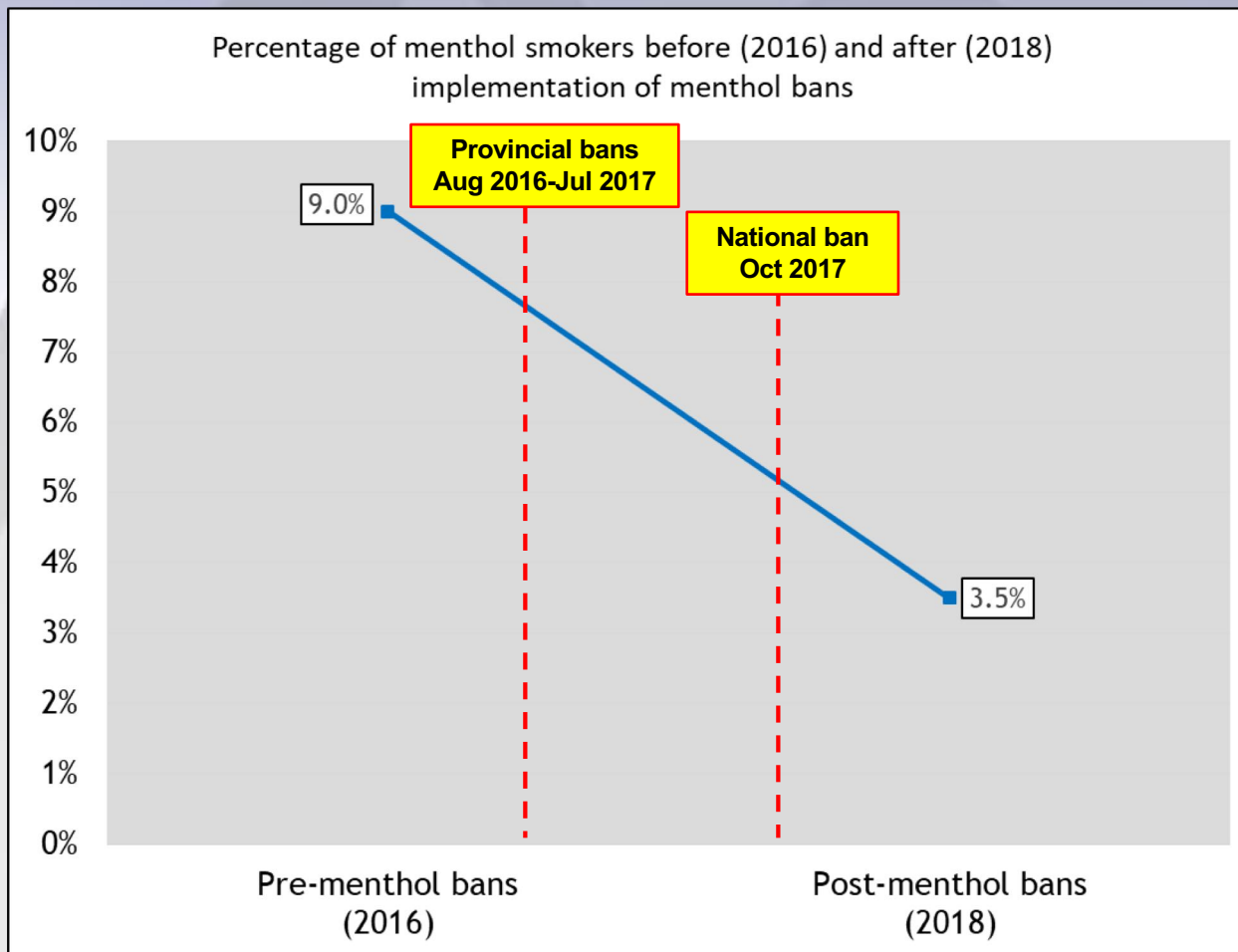
Methods: Participants and study design

- Canadian data from 2016 and 2018 ITC Four Country Smoking and Vaping (4CV) Surveys
- 1319 adult (18+ years) smokers
 - 1169 non-menthol smokers
 - 150 menthol smokers
- Surveys conducted before (2016) and after (2018) implementation of menthol bans in 7 provinces: Quebec, Ontario, Prince Edward Island, Newfoundland & Labrador, British Columbia, Saskatchewan, and Manitoba

Menthol bans in Canada and ITC survey waves

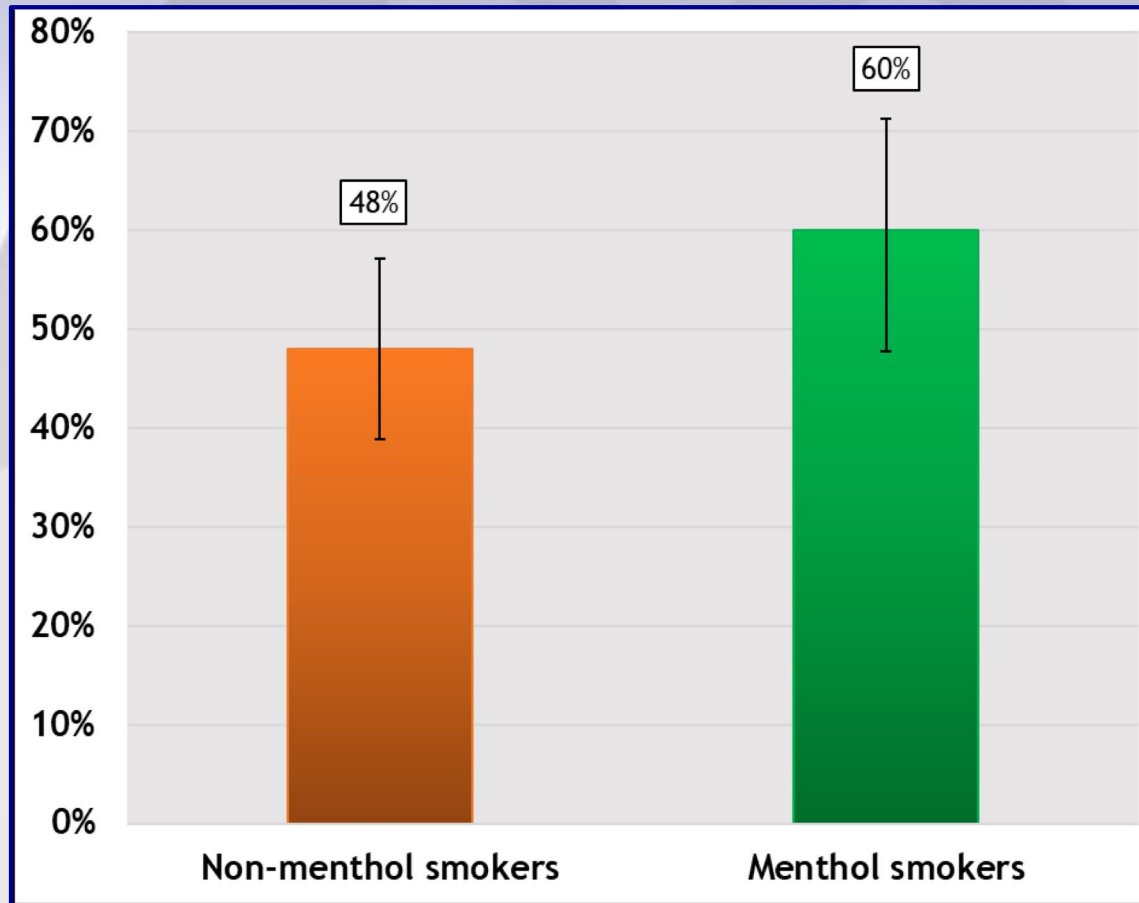


Percentage of menthol smokers, pre- and post-ban



After menthol bans:
Decrease in menthol smoking across all 7 provinces ($p < .001$)

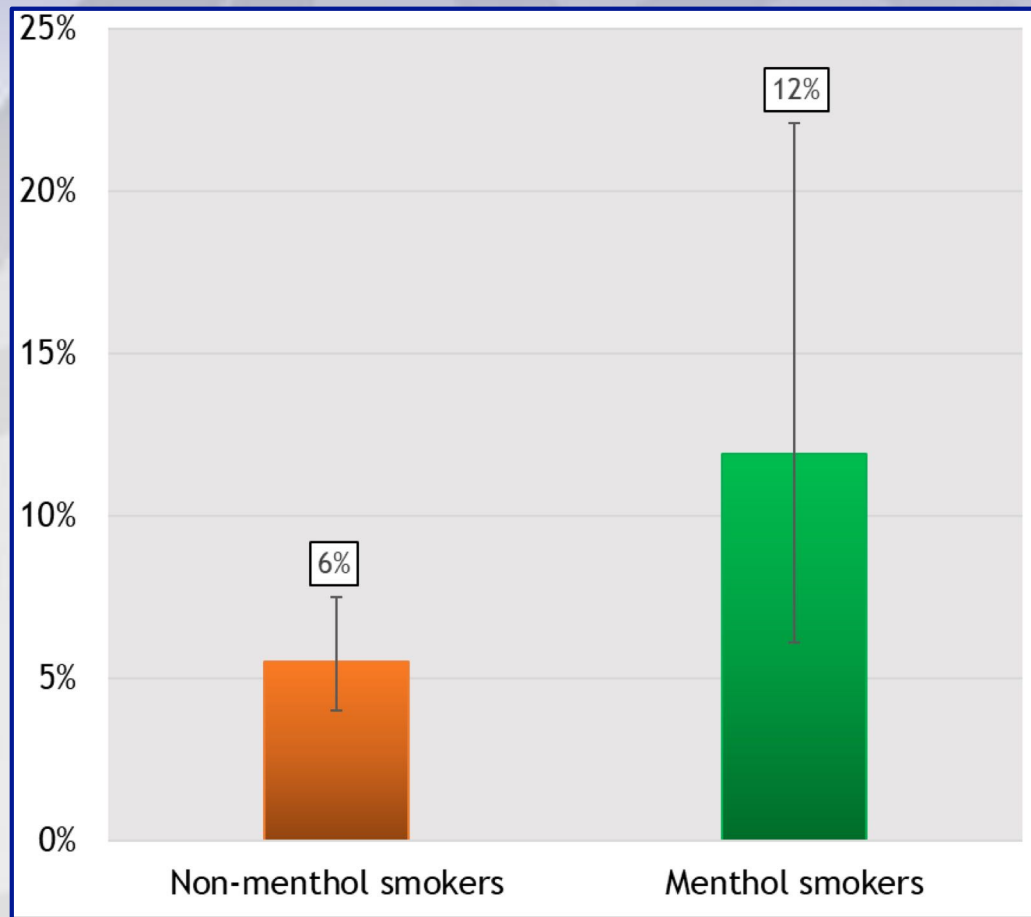
Percentage of menthol and non-menthol smokers who **made a quit attempt** in last 18 months, after menthol bans



After menthol bans:

Menthol smokers more likely than non-menthol smokers to make a quit attempt in last 18 months ($p < .05$)

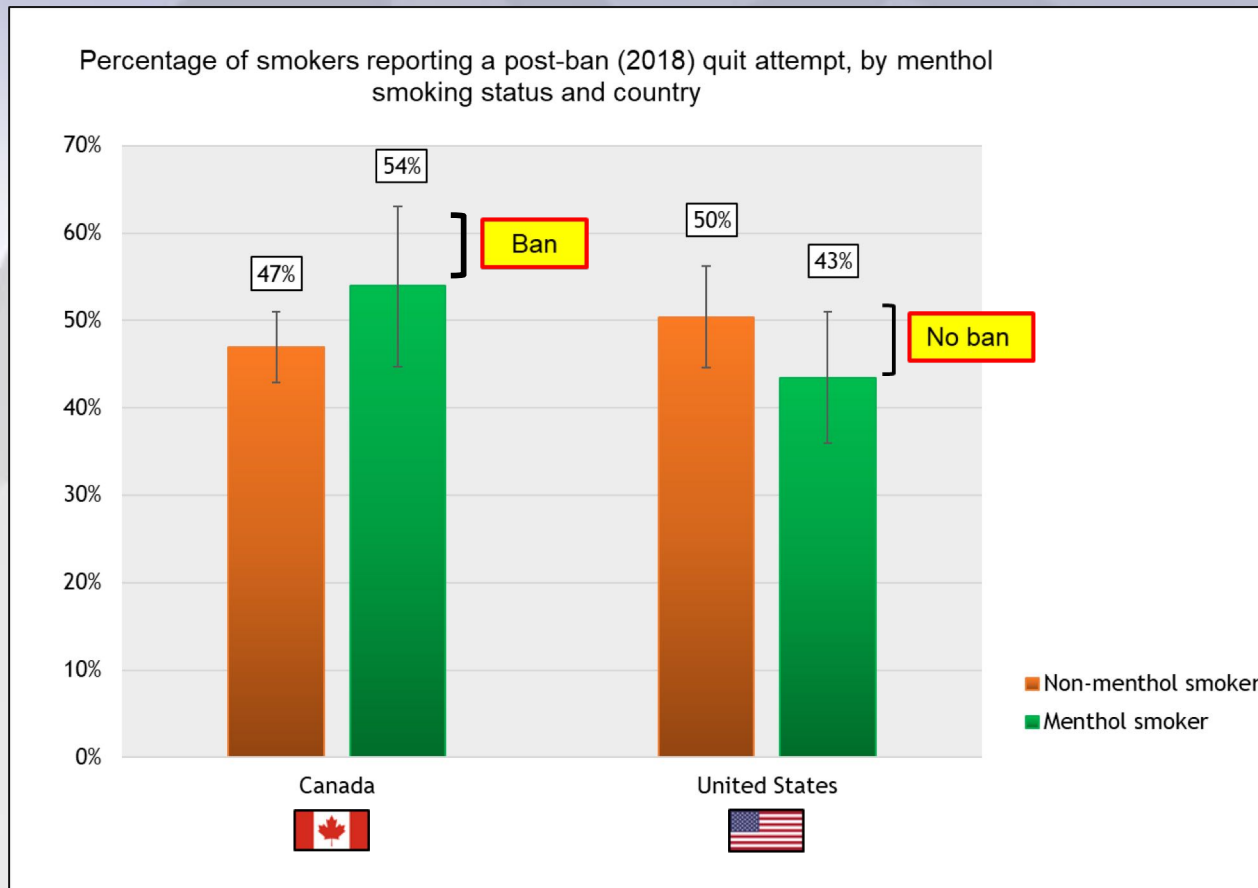
Percentage of menthol and non-menthol smokers who quit smoking >6 months, after menthol bans



After menthol bans:

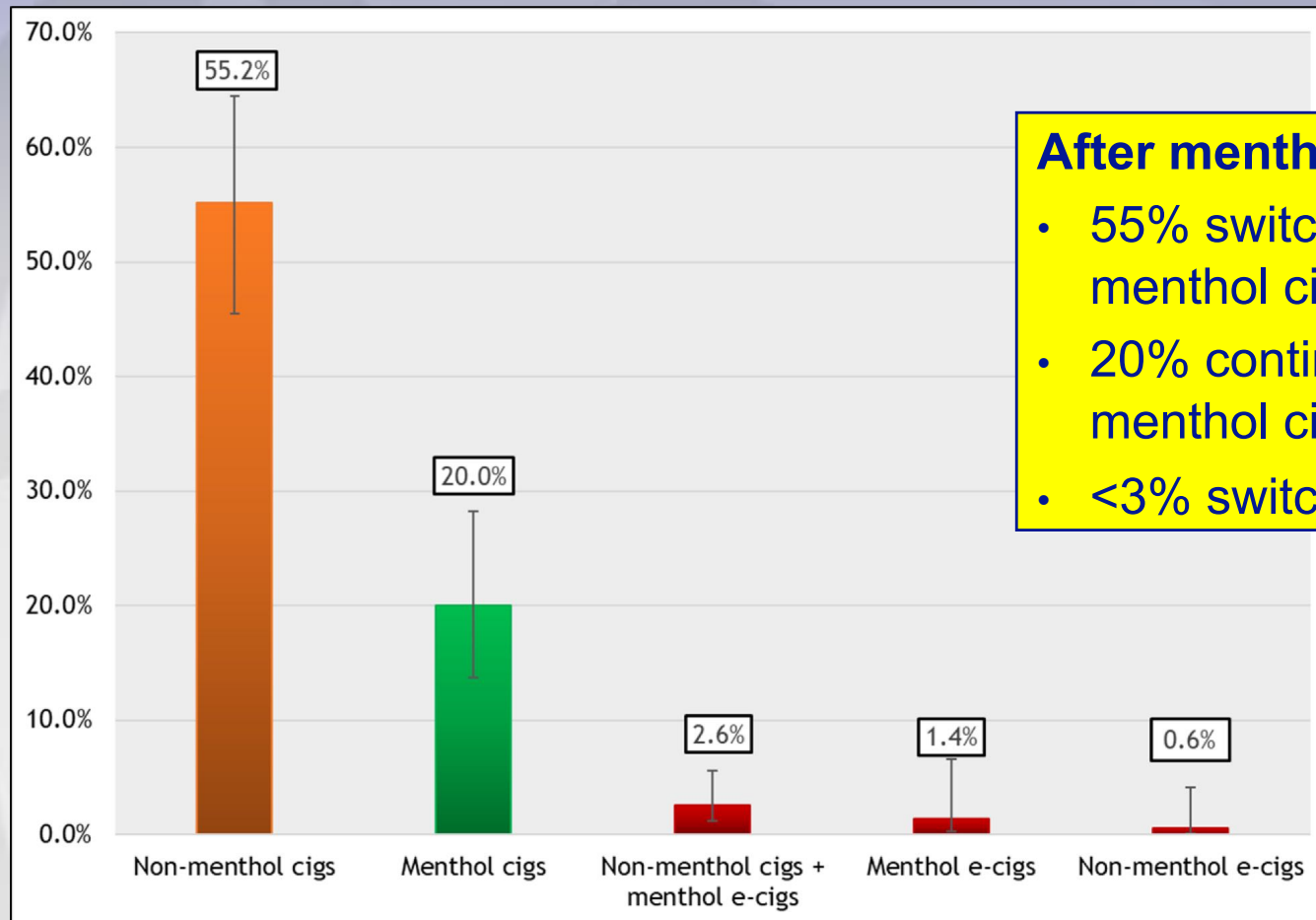
Menthol smokers more likely than non-menthol smokers to have quit smoking for >6 months ($p < .01$)

Differences in quitting for menthol smokers vs. non-menthol smokers in Canada (ban) vs. US (no ban)?



- Menthol smokers in Canada more likely than menthol smokers in the US to make a quit attempt ($p < .05$)
- No differences in quitting for menthol smokers vs. non-menthol smokers in Canada and the US

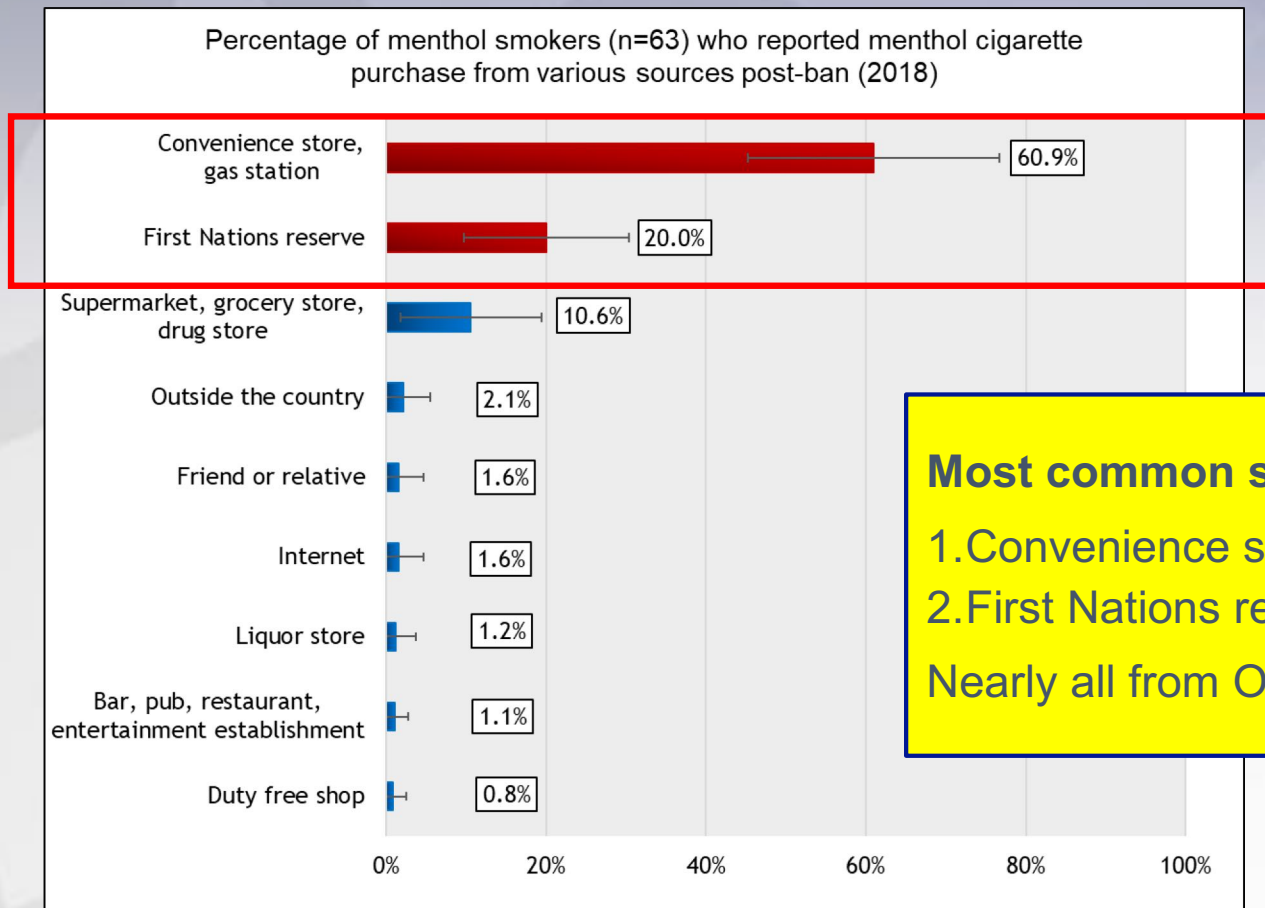
What products did menthol smokers switch to after the menthol bans?



After menthol bans:

- 55% switched to non-menthol cigarettes
- 20% continued to smoke menthol cigarettes
- <3% switched to vaping

Where did menthol smokers get their menthol cigarettes after the menthol ban?



Most common sites of purchase:

1. Convenience stores (60.9%, n=35)
2. First Nations reserves (20.0%, n=11)

Nearly all from Ontario

Non-menthol pack alternatives in retail outlets after menthol ban in Ontario (Borland et al., 2019)



Brief report

Is blue the new green? Repackaging menthol cigarettes in response to a flavour ban in Ontario, Canada

Tracey Borland,¹ Sandra A D'Souza,¹ Shawn O'Connor,¹ Michael Oliver Chaiton,¹ Robert Schwartz^{1,2}

► Additional material is published online only. To view please visit the journal online (<http://dx.doi.org/10.1136/tobaccocontrol-2018-054454>).

¹Ontario Tobacco Research Unit, Dalla Lana School of Public Health, University of Toronto, Toronto, Ontario, Canada

²Centre for Addiction and Mental Health, Toronto, Ontario, Canada

Correspondence to Tracey Borland, Ontario Tobacco Research Unit, c/o Dalla

ABSTRACT

Background As of 1 January 2017, the Canadian province of Ontario banned the distribution and sale of menthol tobacco products. There is limited knowledge about how tobacco companies will adapt their packaging in response to a menthol ban.

Methods We conducted a content analysis of preban traditional menthol (no capsule) and menthol capsule cigarette packs and their postban replacements. Preban and postban packs were matched using tobacco company descriptions of replacement brands in business-to-business marketing materials, advertising on cigarette pack cellophane and a tobacco company website.

Results A total of 63 menthol (n=30) and 'non-

of flavour capsule cigarettes has grown since 2007,² they were only introduced to the Canadian market in late 2015.³ As per tobacco company business-to-business marketing materials, menthol capsule cigarettes were introduced to help adult menthol smokers transition into non-menthol cigarettes (online supplementary figure S1). However, a growing body of research demonstrates that flavoured capsule products are designed to appeal to younger demographics⁴⁻⁶ and that youth and young adults find them more appealing than other age groups^{2,5,7}. In 2016, 6.7% of cigarette sales in Ontario were menthol.⁸ Preban, approximately 25% of Ontario high school youth who smoked

Blue was the most common pack colour and brand descriptor after the menthol ban.

Industry response before the menthol ban (May 2020) in the European Union/United Kingdom

PACK IT IN Tobacco firm's new Rizla cards to get round 2020 menthol cigarette ban slammed by charity

Gemma Mullin, Digital Health Reporter
3 Jan 2020, 10:18 | Updated: 3 Jan 2020, 10:27



A TOBACCO firm has been blasted over its new range of Rizlas to get round the menthol cigarette ban which comes into effect this year.

Imperial Tobacco launched Rizla Flavour Infusions - 'cards' that can be used to add a menthol flavour to [traditional tobacco products](#).



Imperial Tobacco is rolling out Rizla Flavour Infusions which are cards that can be inserted to cigarette or tobacco packets Credit: RIZLA

JTI adds menthol cigarillos to portfolio

By Ellis Cronin in Tobacco 10th January 2020

Print

Tobacco company JTI has launched Sterling Dual Capsule Leaf wrapped cigarillos.



The King Size variant is available in a 10-pack size, retailing at £4.50, and contains a Virginia blend tobacco wrapped in a tobacco leaf.

The cigarillos contain a menthol capsule in the filter which when clicked will release a peppermint flavour.

Ross Hennessy, head of sales at JTI UK, said: "We expect that Sterling Dual Capsule Leaf Wrapped cigarillos will become a popular choice for adult smokers and appreciated by those looking for value-for-money tobacco options."



Summary of ITC Evaluation of Canada's Menthol Ban

1. Menthol bans help smokers to quit

- Increase in quit attempts and quitting for menthol smokers vs. non-menthol smokers in Canada (consistent with findings from Ontario)
- Menthol smokers in Canada (ban) more likely to make quit attempt vs. menthol smokers in the US (no ban)
- Virtually no post-ban switching to vaping (either menthol or non-menthol e-cigs)

2. Need to monitor and prevent industry tactics to circumvent menthol bans

- 20% pre-ban menthol smokers continued to smoke menthol cigarettes
- Complete ban on menthol that covers all tobacco products is best
- Need additional measures to eliminate ability of industry to get around menthol ban (e.g., plain packaging, ban on brand descriptors, regulation of cigarette filters)



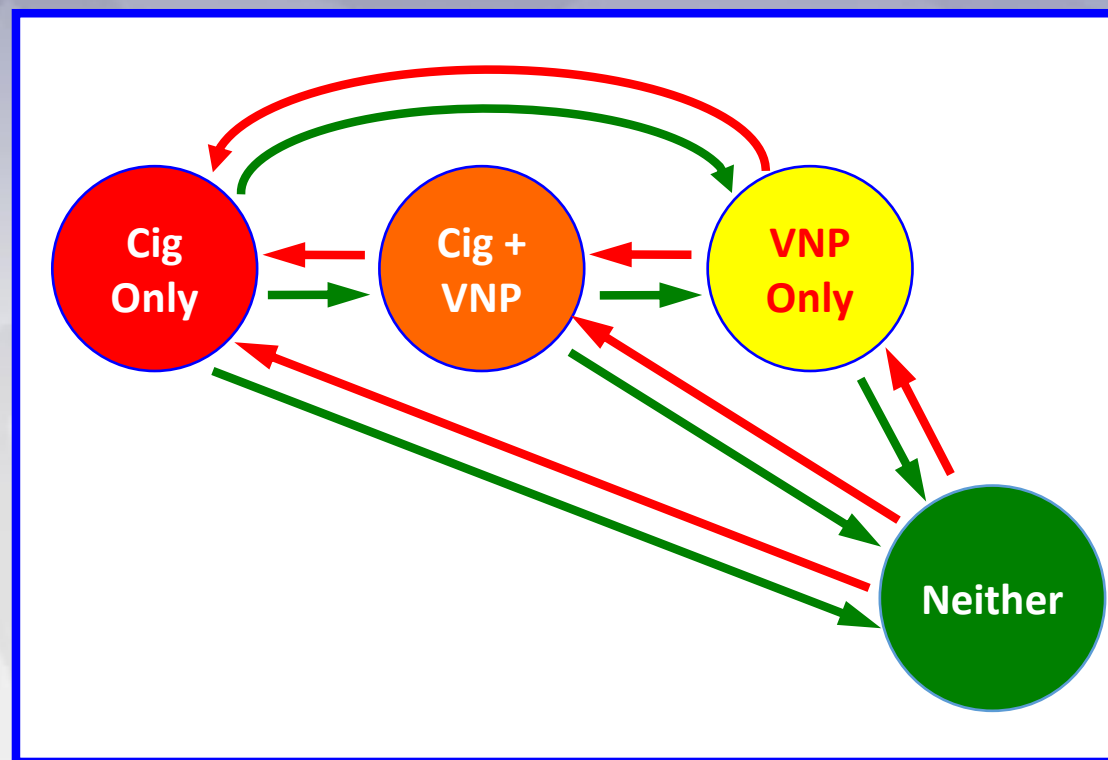
International Tobacco Control
Policy Evaluation Project

Extending the ITC Conceptual Model to Nicotine Vaporized Products

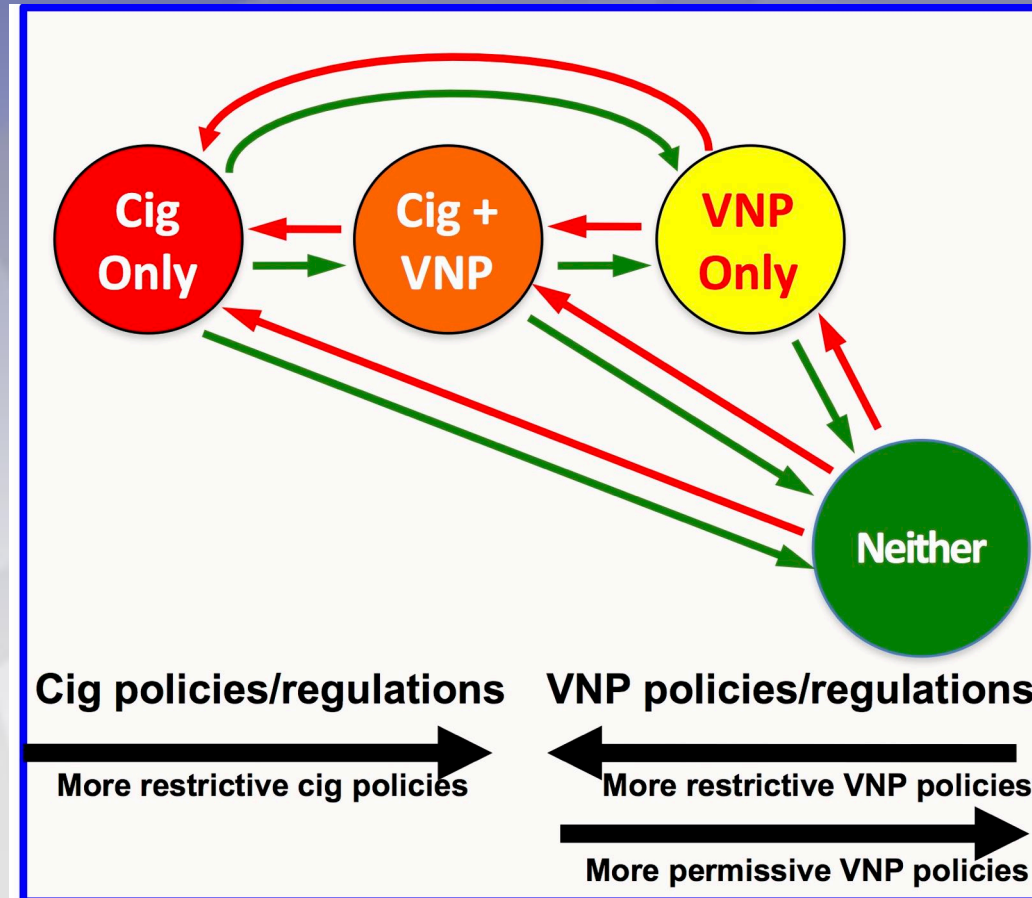
Substitutability and Its Implications

Cigarettes and Vaping Products are Substitutes

- ◆ Underlying assumption of the two key questions about vaping products:
 - Are e-cigarettes a gateway to cigarettes?
 - Do e-cigarettes help smokers quit?
- ◆ Substitutability most familiar for price/tax policies (cross-price elasticity; differential taxation, Chaloupka, Sweanor, & Warner, NEJM 2015)
- ◆ But substitutability has implications for (all) other policy domains:
 - **Advertising.** Analysis of 2010-15 U.S. data: e-cigarette advertising reduces demand for cigarettes. Proposed e-cig advertising ban estimated to increase cig sales by 1.0% (Tuchman, 2019)
 - **Flavor Bans.** Discrete choice expt in US: banning ecig flavors (menthol and/or fruit/sweet) leads to greater demand for cigarettes. (Buckell, Marti, & Sindelar, NBER 2017)

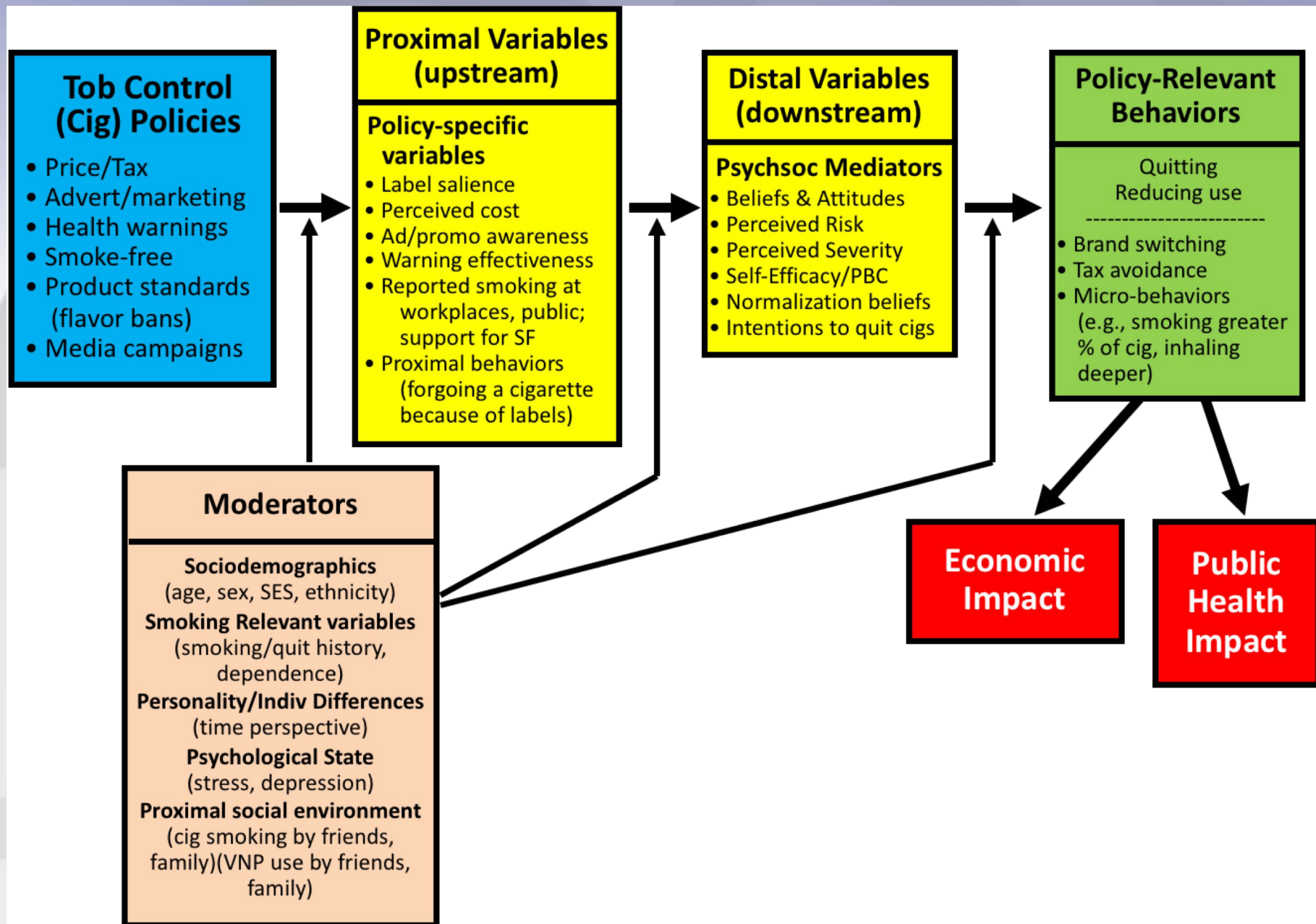


More Harmful to Less Harmful

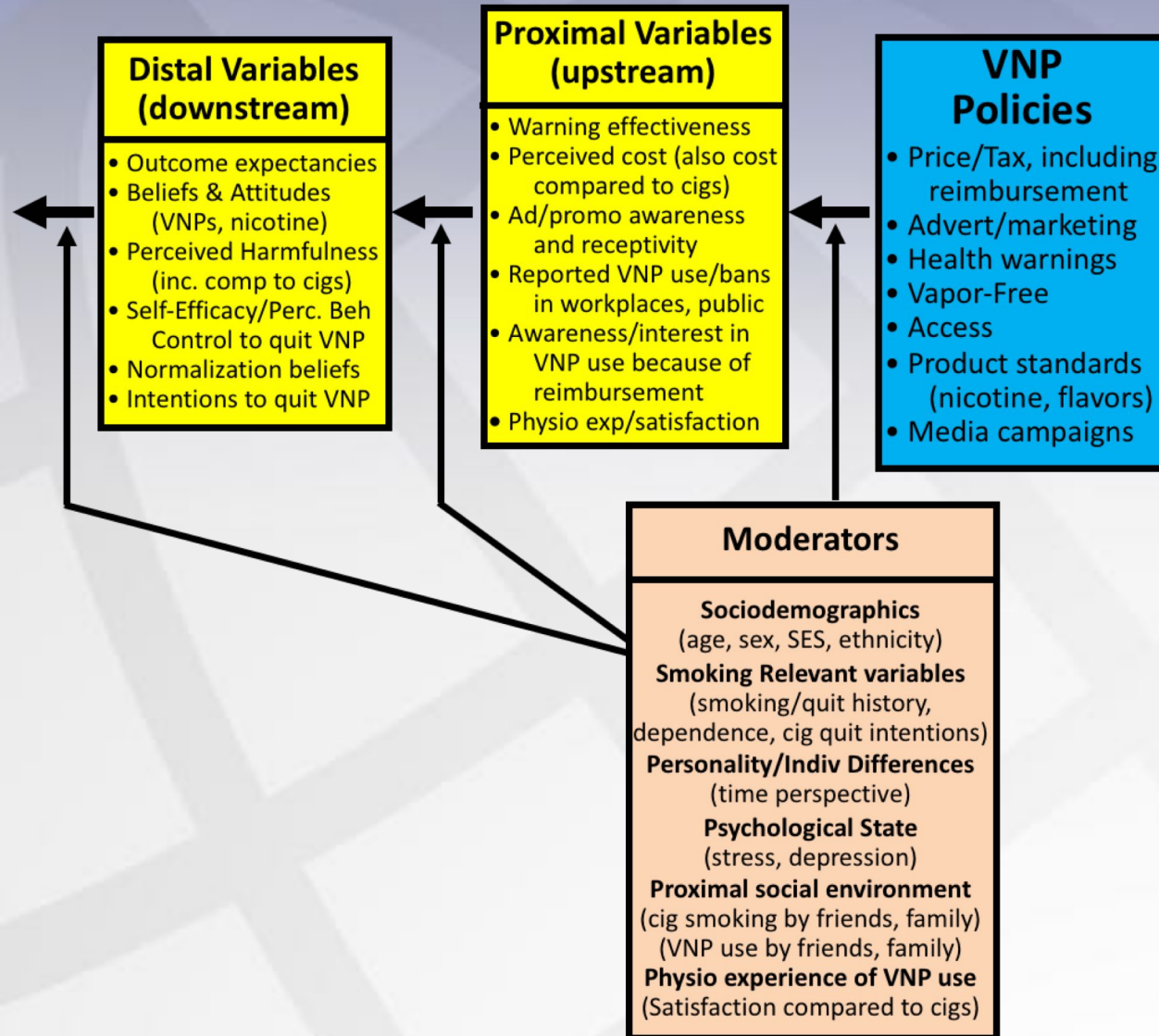


- Cigarette/tobacco control policies all push consumers away from cigarettes.
- But VNP (ANDS/ecig) policies are of two kinds:
 - More restrictive policies (bans, restrictions on access) may PUSH consumers away from VNPs (and possibly toward cigarettes));
 - More permissive policies (differential taxation) may PULL consumers toward VNPs

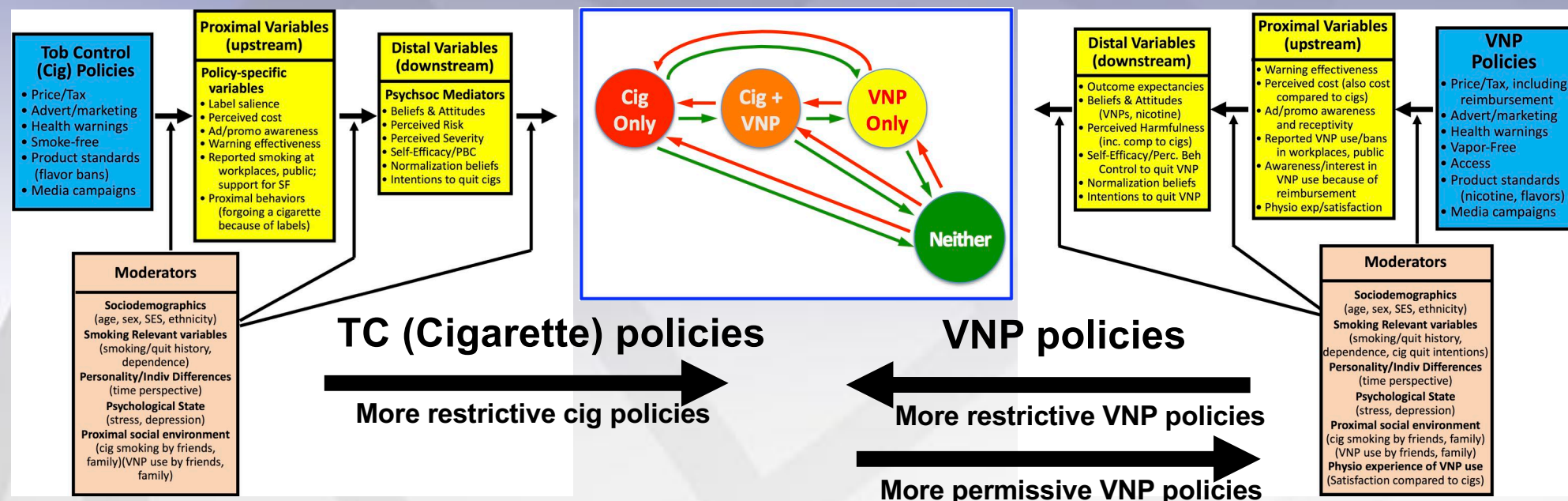
ITC Conceptual Model: for Cigarettes



ITC Conceptual model applied to VNPs



ITC Tobacco Control-VNP Policy Mediation Model



Because cigarettes and VNPs are substitutable goods (this is a matter of DEGREE, not a matter of principle), it is essential to examine the impact of BOTH cigarette policies **AND** VNP policies to examine the impact of “policies/regulations” on use of VNPs, and transitions to/from cigarettes and VNPs.

US National Cancer Institute Program Grant

Evaluating How Tobacco Control Policies are Shaping the Nicotine Delivery Market (P01 CA200512) (Co-PIs: K. Michael Cummings and Geoffrey T. Fong)

Aim 1: To provide a more thorough understanding of how the policy environment influences uptake of and transitions from smoked tobacco to VNPs.

Aim 2: To contribute to the development of methods for monitoring response to VNPs and future alternative nicotine products.

Aim 3: To develop methods to assist policy makers in forecasting the population health impact of different product regulatory schemes.

Five Projects of the ITC P01 Grant

Project 1: Natural History of Cigarette Smoking and VNP Use in Countries with Different Policy Environments

Leader: Geoffrey T. Fong, PhD, University of Waterloo

Project 2: Nicotine and Cigarettes Across Policy Environments

Leader: Richard O'Connor, PhD, Roswell Park Cancer Institute

Project 3: VNP Initiation Among Youth in the US, Canada, and England: Methods to Predict Uptake and Policy Efficacy

Leader: David Hammond, PhD, University of Waterloo

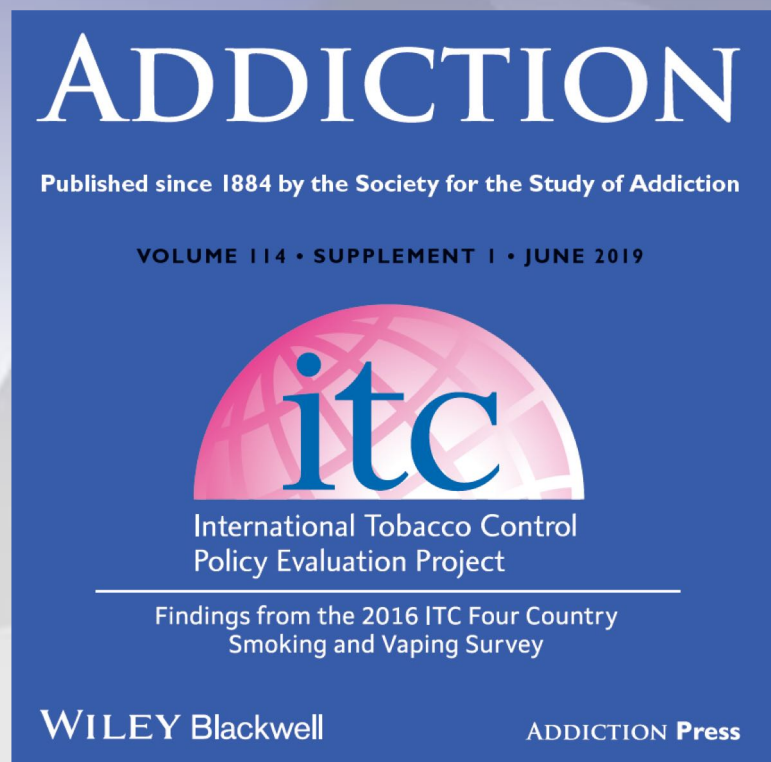
Project 4: The Experimental Tobacco Marketplace (ETM)

Leader: Warren K. Bickel, PhD, Virginia Polytechnic Institute & State Univ

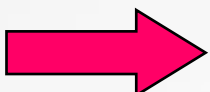
Project 5: Modelling Industry Behaviour and the Use of VNPs on Population Health

Leader: David Levy, PhD, Georgetown University

Project 1 Journal Articles published in 2019



| Lead Author | Title |
|-------------|---|
| Cummings | Predicting the future of smoking in a rapidly evolving nicotine marketplace. |
| Thompson | Methods of the ITC Four Country Smoking and Vaping Survey, wave 1 (2016) |
| O'Connor | Characteristics of nicotine vaping products used by participants in the 2016 ITC Four Country Smoking and Vaping Survey |
| Borland | A new classification system for describing concurrent use of nicotine vaping products alongside cigarettes (so-called 'dual use') |
| Yong | Reasons for regular vaping and for its discontinuation among smokers and recent ex-smokers |
| McNeill | Indicators of cigarette smoking dependence and relapse in former smokers who vape compared with those who do not |
| Chan | Predicting vaping uptake, vaping frequency and ongoing vaping among daily smokers |
| Gravely | Discussions between health professionals and smokers about nicotine vaping products |
| Levy | A modeling approach to gauging the effects of nicotine vaping product use on cessation from cigarettes: what do we know, what do we need to know? |
| Aleyan | Differences in norms towards the use of nicotine vaping products among adult smokers, former smokers and nicotine vaping product users |
| Nahhas | Rules about smoking and vaping in the home |
| Cheng | Prices, use restrictions and electronic cigarette use |
| McDermott | Exposure to and perceptions of health warning labels on nicotine vaping products |



Articles from Project 1 data (4CV Wave 1) other than from the Addiction supplement

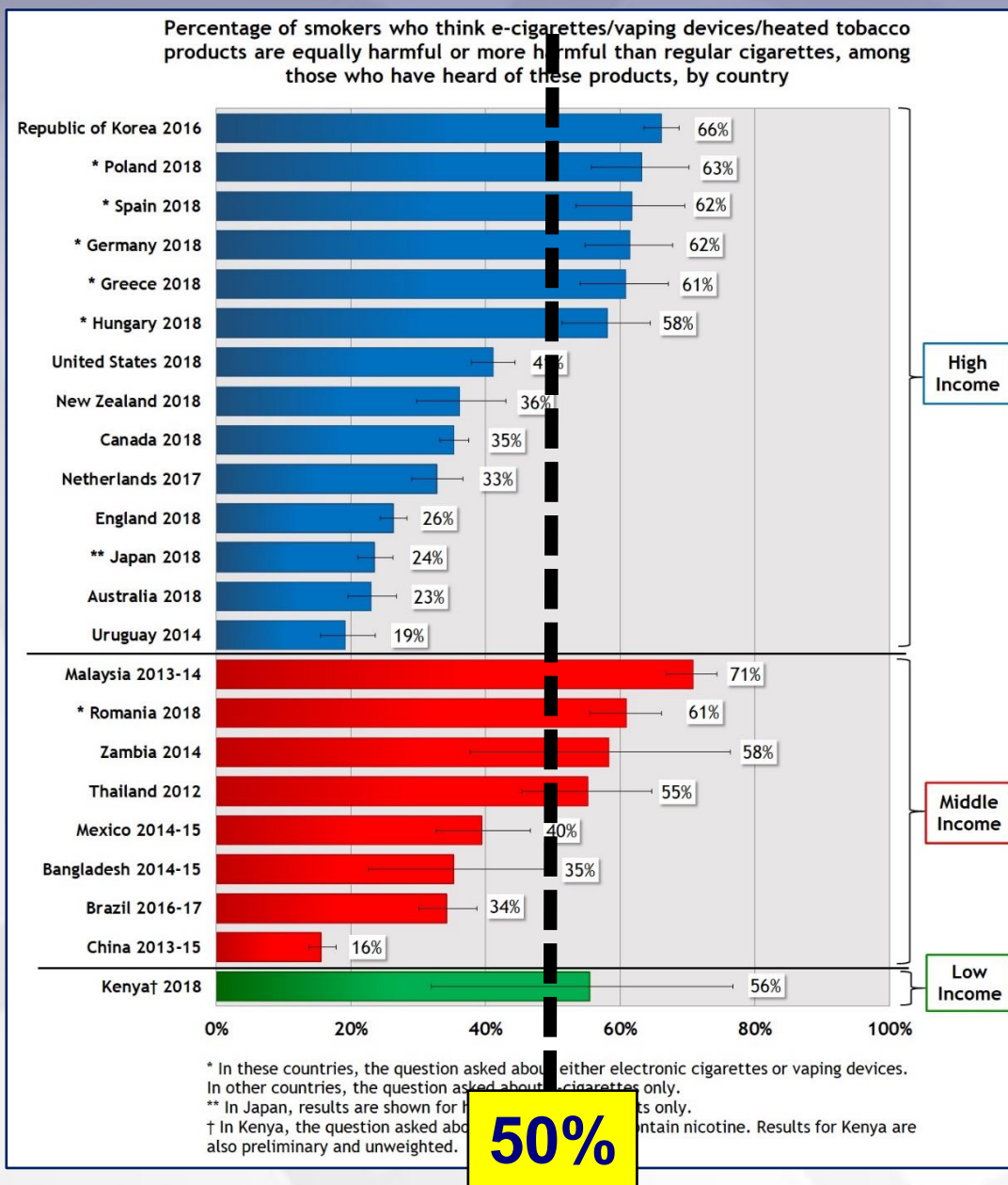
| Lead Author | Title |
|-------------|--|
| Braak | Where do vapers buy their vaping supplies? |
| Heckman | Longer duration of smoking abstinence is associated with waning cessation fatigue. |
| Li | How are self-reported physical and mental health conditions related to vaping activities among smokers and quitters? |
| Cho | Cross-country comparison of cigarette and vaping product marketing exposure and use. |
| Gravely | Prevalence of awareness, ever-use and current use of nicotine vaping products (NVPs) among adult current smokers and ex-smokers in 14 countries with differing regulations on sales and marketing of NVPs. |
| Levy | An Examination of the Variation in Estimates of E-Cigarette Prevalence among U.S. Adults. |
| Li | The association between smokers' self-reported health problems and quitting. |
| Cheng | Costs of vaping. |



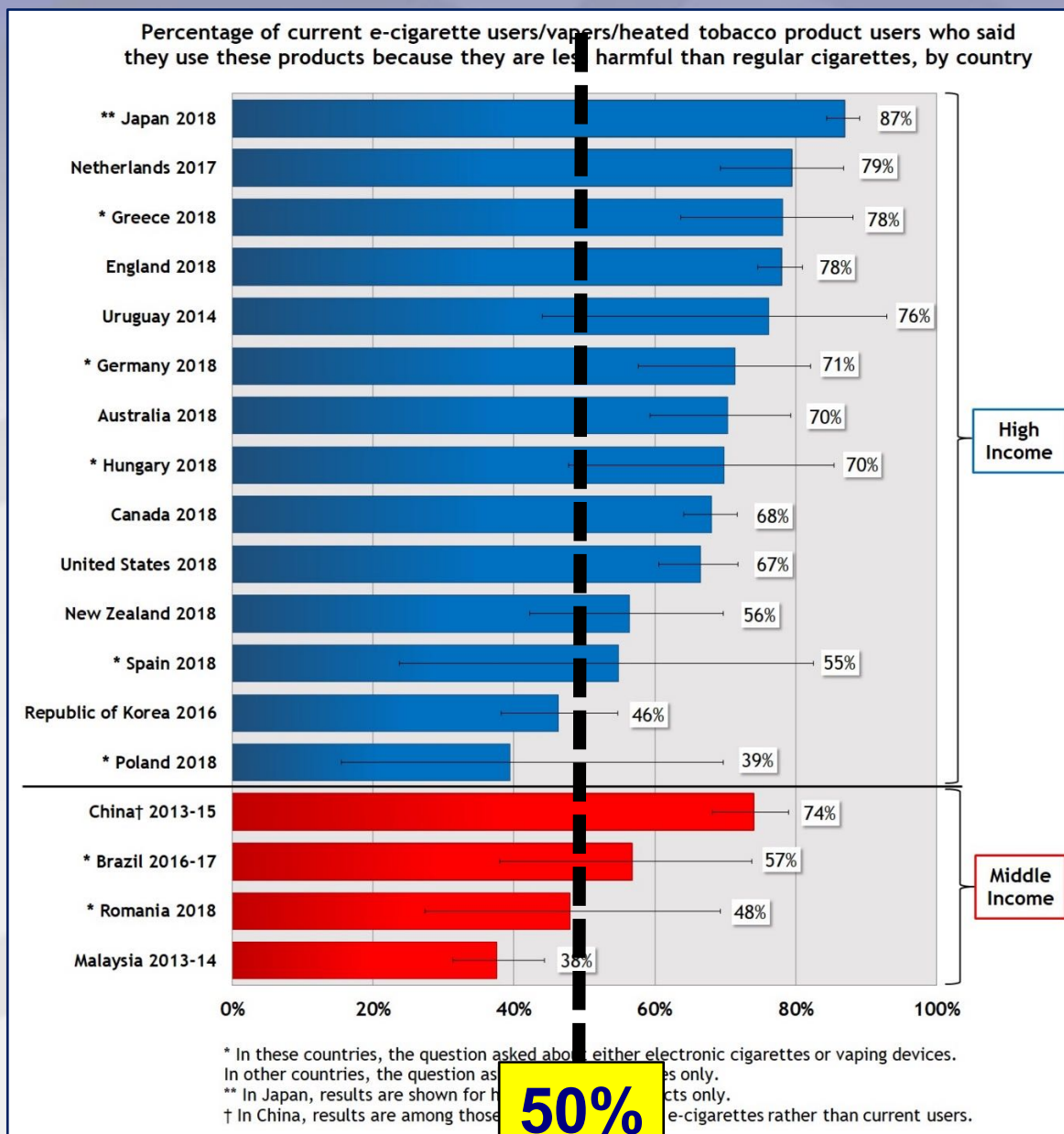
International Tobacco Control
Policy Evaluation Project

Cross-Country Data on E-Cigarettes

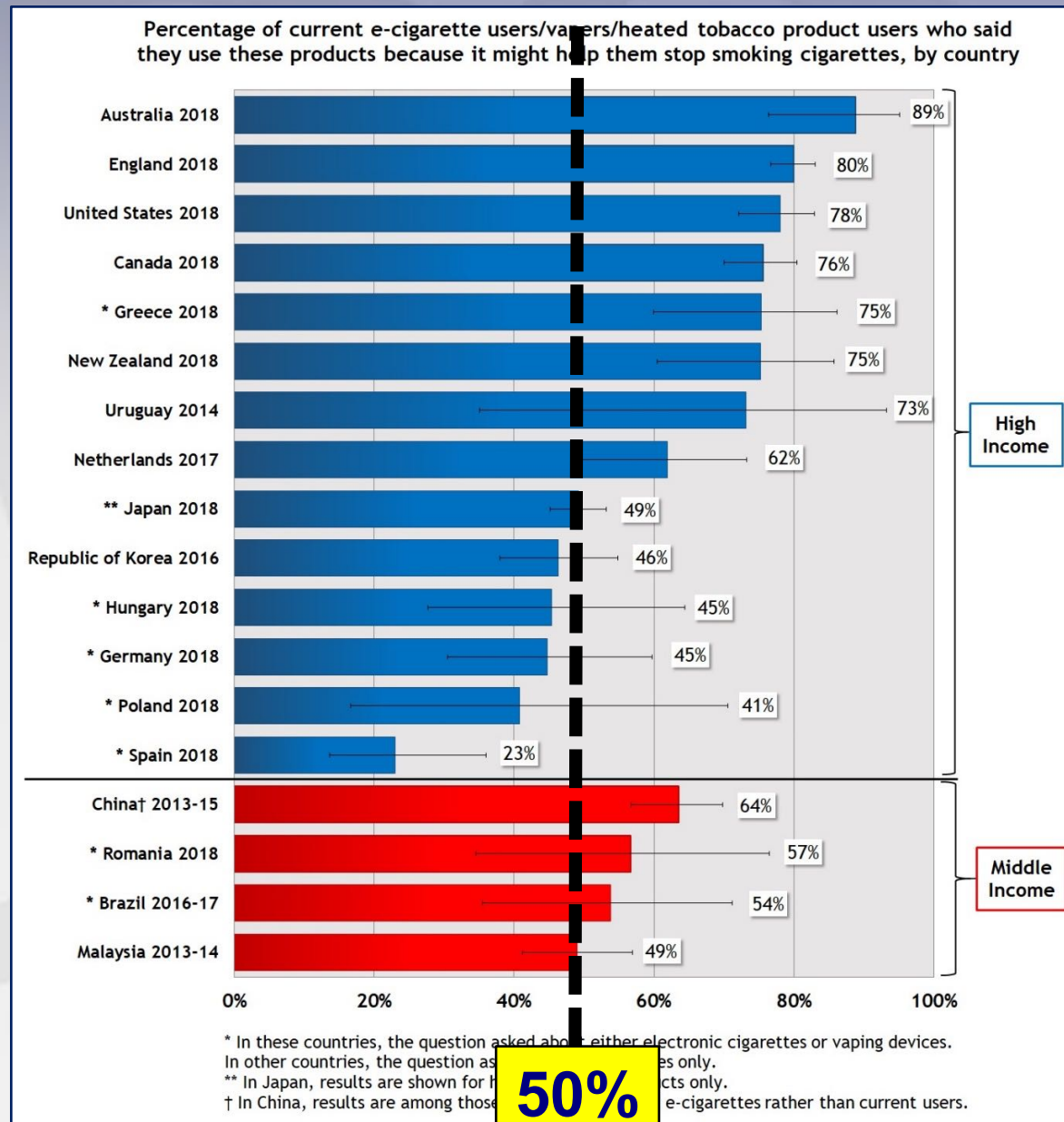
Belief that E-Cigarettes are Equally/More Harmful



Reasons for Using E-Cigarettes: Less Harmful



Reasons for Using E-Cigarettes: To Help Quit





International Tobacco Control
Policy Evaluation Project

Heated Tobacco Products



Your IQOS 3.
 Your way.

Create the perfect look for you with a host of color and accessory containers to explore.
 Find out more about the IQOS range at iqos.com

IQOS 3
 This changes everything

成人向けの喫煙製品には健康被害があり、リスクがないわけではありません。
 ©2014 Philip Morris Inc. All rights reserved.

喫煙は、あなたにとって肺がんの原因の一つとなり、心筋梗塞・脳卒中の危険性や肺気腫を悪化させる危険性を高めます。未成年者の喫煙は、健康に対する悪影響やたばこへの依存をより強めます。周りの人から勧められても決して吸ってはいけません。人により程度は異なりますが、ニコチンにより喫煙への依存が生じます。



新型 IQOS 誕生。 選べる2つのスタイル。

No.1加熱式たばこ
IQOS 3
This changes everything



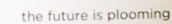
成人喫煙の健康被害は喫煙者だけでなく、周囲の人も受けとります。© 2018 Philip Morris Inc. 本製品はタバコを吸うための道具であり、喫煙行為そのものが健康被害の原因となります。喫煙は健康に悪影響を及ぼす可能性があります。

The image shows a retail display for Marlboro IQOS products. At the top center, a blue sign indicates that the products are 'iQOS製品' (iQOS Products) and are '割引対象外' (Not eligible for discount) / 'Non-discountable'. Below this, the products are arranged in rows within a light-colored wooden tray. On the left, two large black and white rectangular cases are shown, each with a price tag of ¥10,160. In the center, there are three rows of Marlboro IQOS product boxes: the top row has blue and teal boxes, the middle row has blue and teal boxes, and the bottom row has a blue box and a green box. To the right of the boxes, there are two more large black and white rectangular cases, each with a price tag of ¥8,300. The background is a light-colored wooden wall.

[illegible]

Real tobacco without smoke* smell or ash.
PLOOM TECH

PLOOM TECH

[illegible]

iQOS Store in Tokyo



iQOS Store in Toronto



FDA NEWS RELEASE

FDA permits sale of IQOS Tobacco Heating System through premarket tobacco product application pathway

Agency places stringent marketing restrictions on heated tobacco products aimed at preventing youth access and exposure to the new products

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For Immediate Release: April 30, 2019

The FDA is continuing its substantive scientific review of the company's MRTP applications. The company would need to receive an MRTP order from the FDA before they could market a tobacco product with any implicit or explicit claims that, among other things, a product reduces exposure to certain chemicals or that use of the product is less harmful than another tobacco product or would reduce the risk of disease. If a company markets a tobacco product as an MRTP without authorization, the company would be in violation of the law and may face FDA advisory or enforcement actions.

FDA Authorizes Marketing of IQOS Tobacco Heating System with 'Reduced Exposure' Information

Agency Will Closely Monitor Real-World Data to Assess if Marketing Continues to be Appropriate

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For Immediate Release: July 07, 2020

Today's action pertains to the separate MRTP applications for these products and further authorizes the manufacturer to market these specific products with the following information:

"AVAILABLE EVIDENCE TO DATE:

- The IQOS system heats tobacco but does not burn it.
- This significantly reduces the production of harmful and potentially harmful chemicals.
- Scientific studies have shown that switching completely from conventional cigarettes to the IQOS system significantly reduces your body's exposure to harmful or potentially harmful chemicals."

Even with this action, these products are not safe nor "FDA approved." The exposure modification orders also do not permit the company to make any other modified risk claims or any express or implied statements that convey or could mislead consumers into believing that the products are endorsed or approved by the FDA, or that the FDA deems the products to be safe for use by consumers.

IQOS and HTPs in Japan

- IQOS introduced nationally in Sep 2016
- By Sep 2019—captured 15.5% of the tobacco market (and all HTPs together had captured 21.4%).
- Over the same period: cigarette sales decreased by 30%.
- In just 5 years, IQOS now accounts for 18.7% of PMI's total revenue worldwide and it is sold in 52 countries.
- PMI has projected that IQOS and their other ANDS will comprise >30% of their global sales and 38-42% of their global revenue by 2025.



ITC Japan and Korea Surveys

ITC Korea Team: Hong Gwan Seo, Sungkyu Lee, Sung-il Cho

ITC Japan Team: Yumiko Mochizuki, Itsuro Yoshimi, Takahiro Tabuchi, Kota Katanoda, Tadao Kakizoe

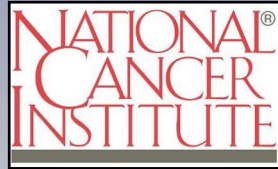
| User Group | Sample Size | |
|----------------------------|-------------|-------|
| | Japan | Korea |
| Exclusive Cigarette Smoker | 2,000 | 2,000 |
| Exclusive HTP user | 1,000 | 500 |
| Exclusive EC user | | 400 |
| HTP-cigarette dual user | 1,000 | 800 |
| EC-cigarette dual user | | 500 |
| Never or Non-user | 500 | 500 |
| Total | 4,500 | 4,700 |

| Selected measures for Cigarettes, HTPs, and ECs (Appendix 1 = Wave 2 of Japan Survey) | |
|--|--|
| Demographic Variables: Gender, age, ethnicity, education, income, state of health | |
| Other personal moderators: Quitting history, nicotine dependence, levels of stress, including financial stress, depressed mood, use of intoxicants (e.g., alcohol, cannabis), time perspective, etc. | |
| Environmental moderators: Number of smokers/ users in the household, and in social network | |
| Policy-Specific (proximal) measures of FCTC policies (cigarettes) and policies on HTPs/ECs: a) Article 6 (all three product classes: cigarettes, HTPs, and ECs (Korea only)): Price paid per unit of product, total weekly cost, product type/variant, purchasing unit, price perceptions b) Article 14 (all): Use of cessation services & recall of advice, use of HTPs/ECs and/or other medicines use in conjunction with professional assistance, advice on appropriateness of HTPs/e-cigarettes use. c) Article 13 (all): Advertising/ marketing: noticing ads and frequency in key channels (TV, print, internet), susceptibility to advertising, whether HTP/EC advertising makes them think about cigarettes. d) Article 11 (all): Health warnings: salience and noticing of health warnings (if any), brand usage, perceived risks, perceived impact on product use; forgoing cigarettes because of the warnings. e) Article 8 (all): Smoke-free/Vapor-free laws (and/or establishment policies): exposure to smoking/vaping in key venues, perceived impact of laws/policies on product use, reports on restrictions f) Product availability (HTPs/ECs): Restrictions on access: perceived availability g) Article 9 (mostly HTPs/ECs): Nicotine content, flavor and other characteristics: nicotine content and flavors of HTP/EC brands used, perceived addictiveness of HTPs, ECs, cigarettes, appeal of HTPs/ECs. h) Article 12 (both): Awareness/recall of media campaigns on HTPs/ECs, and on anti-smoking themes. | |
| Psychosocial Mediator (distal) variables (all): Knowledge/awareness/beliefs about harmfulness of cigarettes, HTPs, ECs, Social norms for HTPs, ECs, and cigarettes, outcome expectancies for products, reasons for using HTPs / ECs, self-efficacy and intentions to quit smoking; perceived harmfulness of HTPs and ECs relative to cigarettes, health concerns, functions of smoking. | |
| Tobacco/Nicotine use behaviors (all): History and current levels of use: frequency, duration, intensity of use (e.g., cigarettes/day), usual brand/type of product; History of smoking quit attempts, use of targeted questions about last quit attempt (timing, length, aids used, duration of abstinence, reasons for success/relapse); product switching + reasons for switching (+ reasons for starting/quitting HTPs, ECs) | |

Summary

- ◆ The global tobacco epidemic is being addressed by the FCTC, but there are challenges in implementation.
- ◆ Evidence systems designed to **evaluate** FCTC policies to strengthen and accelerate implementation of the treaty
- ◆ ITC Project is designed for these evaluation efforts.
- ◆ Recent findings on impact of menthol ban in Canada show that menthol bans are beneficial. US should (finally) move forward
- ◆ Current/future directions: alternative nicotine products: e-cigarettes (vaping products) and the new heated tobacco products such as IQOS, which are now being sold in the US.
- ◆ ITC Cohort Surveys are ongoing in Japan and Korea where the industry has been test marketing HTPs.

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

Geoffrey T. Fong: gfong@uwaterloo.ca
www.itcproject.org

ITC Project Research Organizations



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