

THEME: *Translating tobacco control science into practice*

Our Goal:

To build the scientific evidence base for effective tobacco control policies and programs implemented in different countries as part of the FCTC

Who we are, funding support and productivity

- 90+ investigators from 35 institutions and 19 countries
- So far, NCI's \$7.6M investment in our TTURC has yielded \$30M in additional funding from other sources (mostly outside the US)
- 100+ peer reviewed papers, 200+ scientific presentations



Core support provided by the U.S. National Cancer Institute to the Roswell Park TTURC (P50 CA111236)



Additional major funding provided by the Canadian Institutes of Health Research



3 Projects and 2 Cores

Project 1- *Tobacco Control Policy Evaluation in Developed Countries*
(US, UK, Canada, Australia)

Project 2- *Tobacco Control Policy Evaluation in Developing Countries*
(Thailand and Malaysia)

Project 3- *Policy Effects on Cigarette Design, Emissions & Behavior*
(joint effort with CDC to track a cohort of leading cigarette brands
in different countries)

Data Management Core- *coordinates data collection and analysis*
across all studies

Administrative Core- *coordinates communications and administers*
developmental and training resources

Common Features of Projects

◆ Natural experiments

- RCTs not possible
- Strategic selections of countries based upon policies

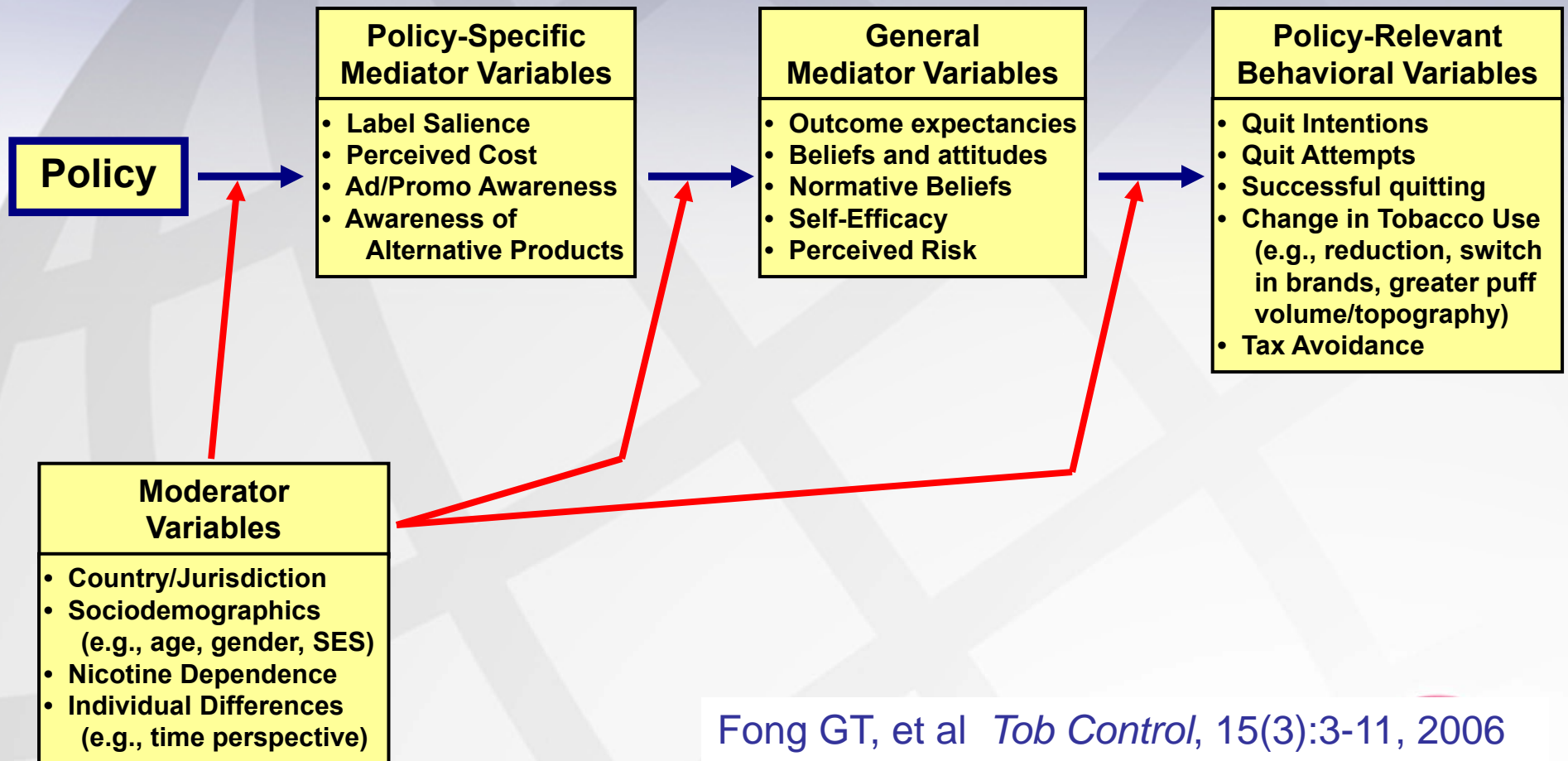
◆ Common data collection protocols

- Extensive use of cohort studies with probability samples of smokers surveyed annually in each country

◆ Common set of measures

- Theory driven mediational model of how policies work

Conceptual Model of the ITC Project

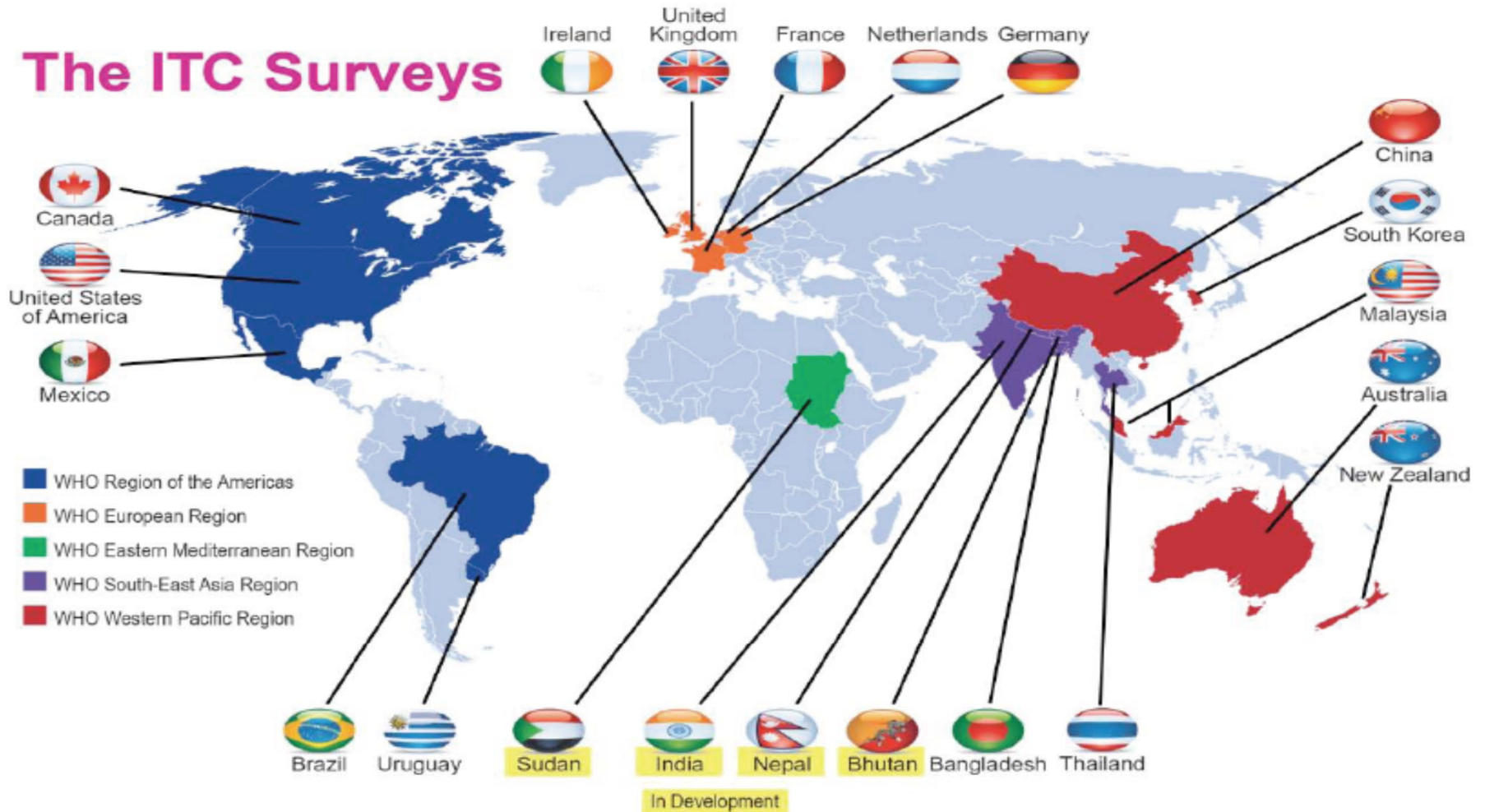


Fong GT, et al *Tob Control*, 15(3):3-11, 2006
IARC *Handbook on Tobacco*, Vol 12, 2009

ITC 2009...

17 countries, with 4 more in development

The ITC Surveys



The FCTC offers a unique, time-limited opportunity to study policy interventions within and between countries

Article 11

Packaging and labelling of tobacco products

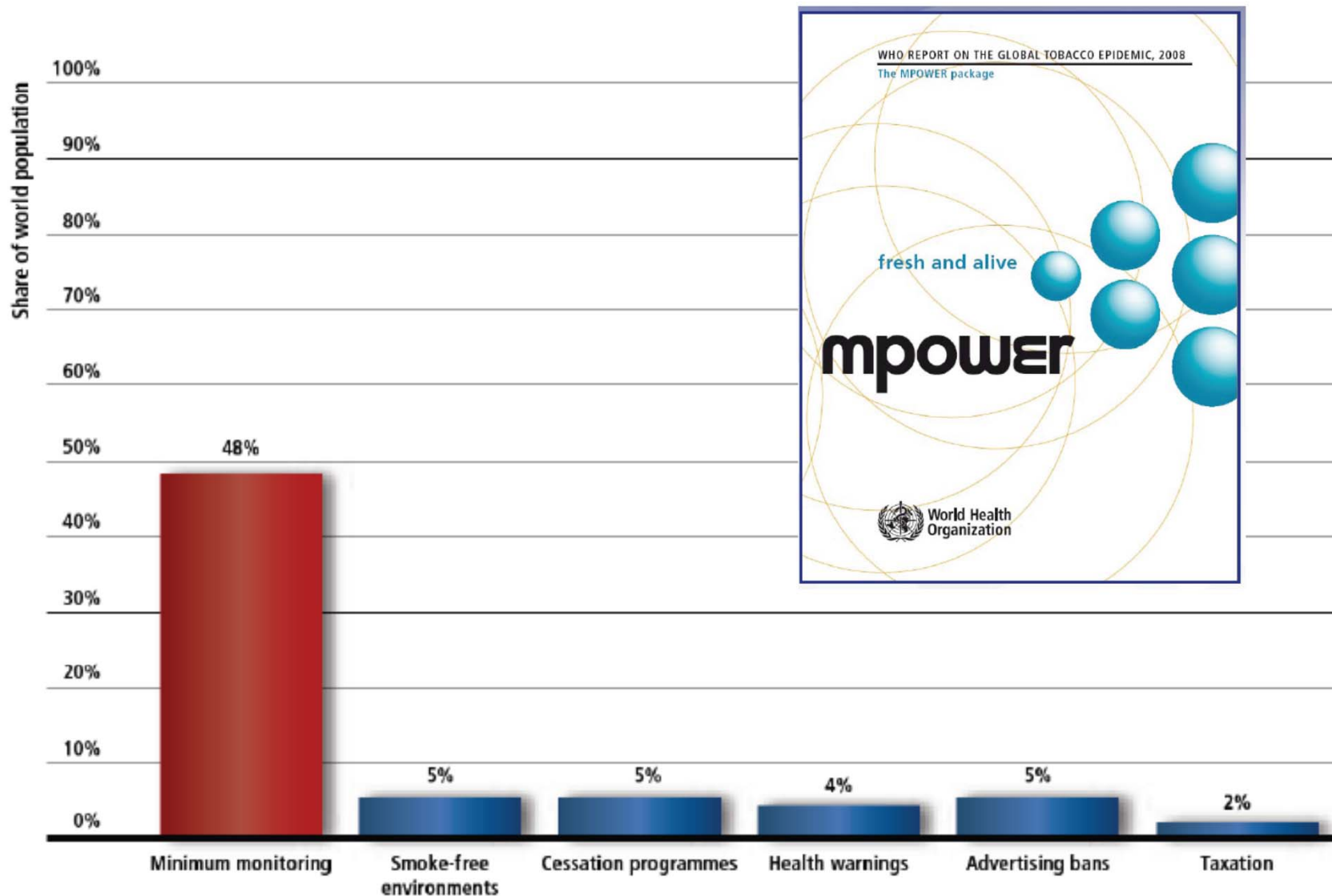
1. Each Party shall, within a period of three years after entry into force of this Convention for that Party, adopt and implement, in accordance with its national law, effective measures to ensure that:

(a) tobacco product packaging and labelling do not promote a tobacco product by any means that are false, misleading, deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions, including any term, descriptor, trademark, figurative or any other sign that directly or indirectly creates the false impression that a particular tobacco product is less harmful than other tobacco products. These may include terms such as “low tar”, “light”, “ultra-light”, or “mild”; and

An urgency to act. Over 100 countries must enhance their warning labels within 3 years

What does effective mean?

SHARE OF THE WORLD POPULATION COVERED BY TOBACCO CONTROL POLICIES



How does this relate to the US?

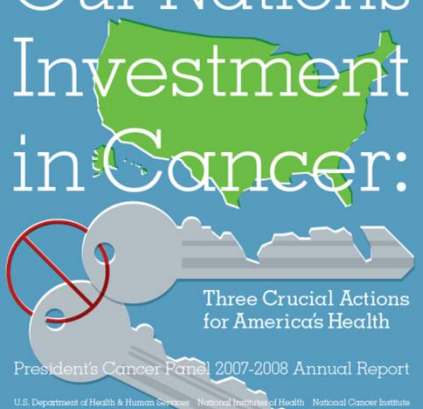
“Reducing tobacco use – the nation’s leading cause of cancer death – remains the greatest unmet potential for improving control of cancer and many other chronic diseases.”

James H. Doroshow, Robert T. Croyle, John E. Niederhuber,
The Oncologist, 2009

“The scourge of tobacco in America must end. Ridding the nation of tobacco is the single most important action needed to dramatically reduce cancer mortality and morbidity.”

2007-2008 Annual Report President’s Cancer Panel

Maximizing
Our Nation's
Investment
in Cancer:

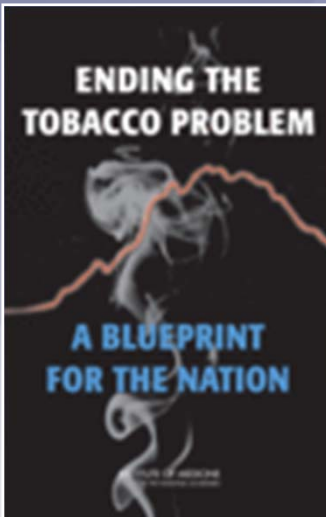


Three Crucial Actions
for America's Health

President's Cancer Panel 2007-2008 Annual Report

U.S. Department of Health & Human Services National Institutes of Health National Cancer Institute

ENDING THE
TOBACCO PROBLEM




A BLUEPRINT
FOR THE NATION

INSTITUTE OF MEDICINE
NATIONAL ACADEMIES PRESS

Harm reduction in
nicotine addiction

Helping people who
can't quit

A report by the Tobacco Advisory Group of the Royal College
of Physicians, October 2007




Royal College
of Physicians
Setting higher medical standards

Call for more research on ways to speed up population level changes in tobacco use behaviors to minimize tobacco related deaths


The Health Consequences
of Smoking

A Report of the Surgeon General



Department of Health and Human Services

NIH State-of-the-Science Conference Statement on
Tobacco Use: Prevention, Cessation, and Control




NIH Consensus and State-of-the-Science Statements

Volume 23, Number 3
June 12-14, 2006

Best Practices

for Comprehensive
Tobacco Control
Programs

October 2007





House Votes to Let F.D.A. Regulate Tobacco

What happens if the FDA regulates tobacco products?

- ✓ **New product warning labels**
 - ✓ **Regulation of product labeling and disclosure**
 - ✓ **Limits on product marketing**
 - ✓ **Product standards to reduce harm**
- ✓ Research on the effectiveness of FCTC policies implemented in other countries can inform the US FDA's efforts to regulate tobacco

ITC Evaluation of FCTC Policies (Partial List)

◆ Warning labels

- UK (2003): Text
- UK (2009): Graphic
- Thailand (2006): Graphic
- Australia (2006): Graphic
- Canada (2010): Graphic, Rd 2
- China (2008): Text
- Mexico (2008): Graphic
- Uruguay (2006,09): Graphic
- Brazil (2008/09): Graphic, Rd 3
- Malaysia (2008): Graphic
- India (2008/09): Graphic

◆ Taxation

- Multiple countries (ongoing)

◆ Product policies

- UK (EU): 10-1-10 regulation
- US/Canada: RIP
- All: product; product x behavior

◆ Illicit trade

- China (2008): prevalence

◆ Advertising/Promotion

- UK (2003): Comprehensive
- Thailand (2006): POS bans
- China (2011): Comprehensive
- Mexico (2008): Comprehensive

◆ Smoke-free

- Ireland (2004)
- Scotland (2005)
- England (2007)
- Uruguay (2006)
- France (2007/08)
- Germany (2007/08)
- China (partial in 2008)
- Netherlands (Part 2–2008)
- Mexico (2008)
- Brazil (2008+)

◆ Light/mild

- UK (2003)
- Australia (2005)
- Canada (2006)



Research Highlights

Eliminate “light” and “mild” and other deceptive product descriptors

FCTC, Article 11

Light Cigarettes

Light cigarettes are believed by smokers to be less harmful

...and as either an alternative to quitting or a step toward quitting

1 mg. tar, 0.1 mg. nic.

Carlton Carlton Carlton Carlton Carlton
Carlton Carlton Carlton Carlton Carlton

10 packs of Carlton have less tar than 1 pack of these brands.

Brand	Tar (mg.)	Nic. (mg.)
Marlboro	16	1.1
Camel	14	1.0
Winston	10	1.1
KENT	12	0.9
5th Avenue	17	1.3

U.S. Gov't. Test Method confirms of all king soft packs.

Carlton is lowest.

SURGEON GENERAL'S WARNING: Smoking By Pregnant Women May Result in Fetal Injury, Premature Birth, and Low Birth Weight.

1 mg. "tar," 0.1 mg. nicotine av. per cigarette by FTC method.

Considering all I'd heard, I decided to either quit or smoke True. I smoke True.

The low tar, low nicotine cigarette. Think about it.

Warning: The Surgeon General Has Determined That Cigarette Smoking is Dangerous to Your Health.

King: 1 mg. tar, 0.1 mg. nicotine av. per cigarette by FTC method.

What is the impact of removing “light/mild”?



What happened to smokers' beliefs about light cigarettes when "light/mild" brand descriptors were banned in the UK? Findings from the International Tobacco Control (ITC) Four Country Survey

R Borland, G T Fong, H-H Yong, K M Cummings, D Hammond, B King, M Siahpush, A McNeill, G Hastings, R J O'Connor, T Elton-Marshall and M P Zanna

Tob. Control 2008;17;256-262; originally published online 21 Apr 2008; doi:10.1136/tc.2007.023812

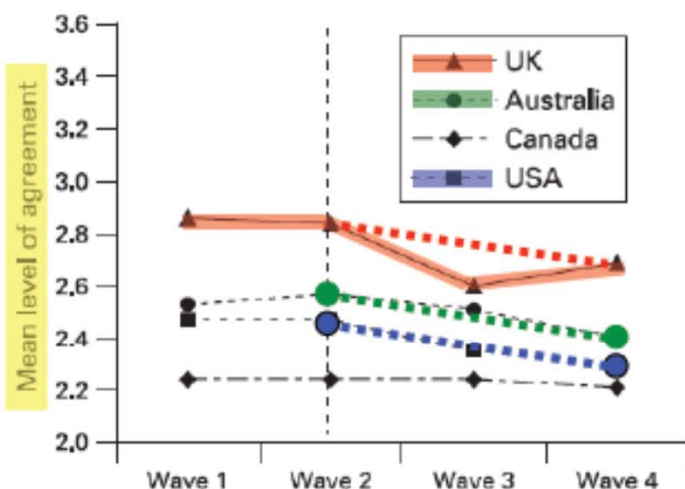


Figure 3 Mean (weighted) level of endorsement of beliefs about health benefit of light cigarettes. The vertical dotted line indicates the date the ban on light brand descriptors took effect in UK.

1. Initial drop in misperceptions (policy + media campaign)
2. Rebounded year later
3. Drop in Australia and U.S. the same over that same period of time w/o lights ban policy.
4. Necessary but not sufficient
5. Industry has other ways of implying reduced harm.

New names for old products



Change in brand descriptions after “light” and “mild” labels were banned in Canada

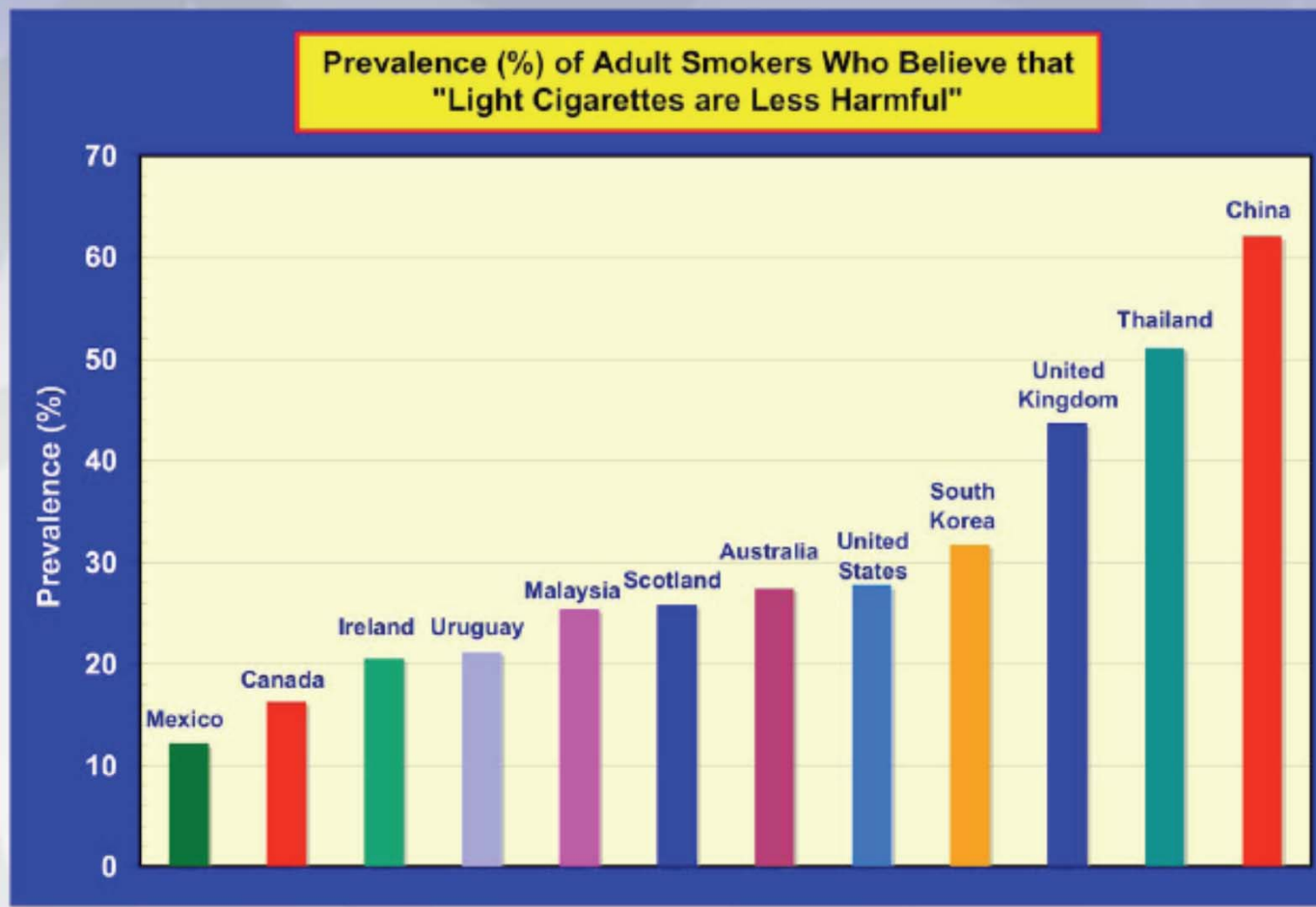


COLOURED WAVE



“Delivers less tar”	30%	70%
“Smoother taste”	27%	73%
“Lower health risks”	28%	72%

Research Evidence as Early Warning System: Beliefs About “Lights” from 12 ITC Countries



China has the highest prevalence of misperceptions about “lights”: need for a strong education campaign

孩子眼中的世界——一切都高高在上，他们更需要被平等的注视。
请在与他们交流时，放低你的身姿。

低一点，更多关爱！

“A little lower means more loving care!”

“Low-harm cigarettes give you more loving care.”

“...the world’s most advanced low-harm cigarette technology, offering a guarantee of health for your smoking life.”



低危害卷烟给您更多关爱！

中南海始终致力于卷烟低危害技术产品的研究与开发，每一款产品都搭载了世界领先的低危害卷烟生产技术，为您的吸烟生活提供健康保证。



A little lower means more loving care! Low-harm cigarettes give you more loving care!

Cigarettes contain conflicting elements of pleasure and harm. Zhongnanhai has always focused on research and development of low-harm cigarette technology. Every product fuses the world’s most advanced low-harm cigarette technology, offering a guarantee of health for your smoking life.

(Advertisement for Zhongnanhai Lights Cigarettes published in the September, 2006 issue of the company’s monthly magazine Zhongnanhai World.)

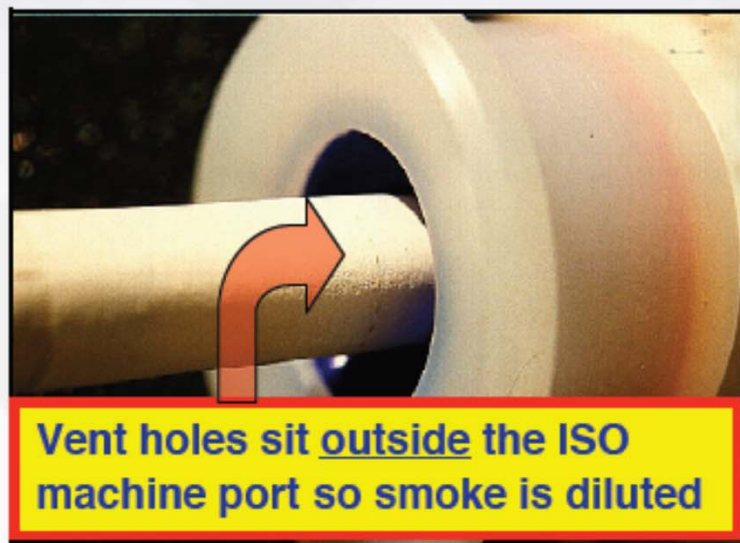


Emissions testing & product disclosures

- FCTC, Articles 9 & 10

Why the **FTC** Testing Method is Invalid as a Method for Assessing Health Harm

- ◆ The ISO/FTC protocol is set at much lower puff volumes and less frequent puffs than the average smoker
- ◆ Tobacco companies have deliberately designed “light” brands to defeat the ISO smoking machine



- ◆ Smokers compensate to get the nicotine dose they need (puffing harder/deeper; covering vent holes)
- ◆ Result: ISO ratings are invalid; “lights” are **NOT** less harmful

How do different machine testing regimens predict nicotine bioavailability?



Testing Regime	Puff Volume (ml)	Puff Frequency (seconds)	Vent Blockage (%)
ISO	30	60	0
Massachusetts	45	30	50%
Canadian	55	30	100%
Compensatory	Variable	Variable	50%

Machine measurements



puff topography



Salivary cotinine

Cigarette Yields and Human Exposure: A Comparison of Alternative Testing Regimens

1495

David Hammond,¹ Geoffrey T. Fong,² K. Michael Cummings,³ Richard J. O'Connor,³ Gary A. Giovino,³ and Ann McNeill¹

Departments of ¹Health Studies and Gerontology, and ²Psychology, University of Waterloo, Waterloo, Canada; ³Department of Health Behavior, Roswell Park Cancer Institute, Buffalo, New York; and ⁴Division of Epidemiology and Public Health, University College London, London, United Kingdom

Abstract

Objective: There is general agreement that the testing protocol for measuring cigarette smoke constituents—the International Organization for Standardization regimen—is an inappropriate mechanism for evaluating human exposure. Alternative smoking regimens have been introduced in Canada and Massachusetts; however, these regimens have not been evaluated against human smoking behavior and biomarkers of exposure. The objective of this study was to compare measures of smoke volume and nicotine uptake among human smokers against the puffing variables and nicotine yields generated by five different machine smoking regimens: (a) International Organization for Standardization, (b) Massachusetts, (c) Canadian, (d) a Compensatory regimen, and (e) a Human Mimiic regimen. **Methods:** Measures of smoke volume and puffing behavior were recorded for 51 smokers who used a portable smoking topography device for three 1-week trials. Measures of

salivary cotinine were taken at the completion of each week. The cigarette brands smoked by participants were then machine-smoked under five testing regimens, including a human mimic condition where brands were machine smoked using the puffing behavior recorded from human smokers. The total volume of smoke collected from each cigarette and the nicotine, tar, and carbon monoxide yields were recorded.

Results: None of the four machine smoking regimens adequately reflected Human Mimiic Yields of tar, nicotine, and carbon monoxide. In addition, none of the four smoking regimens generated nicotine yields that were associated with actual nicotine uptake in humans.

Conclusions: None of the existing smoking regimens adequately represents human smoking behavior nor do they generate yields associated with human measures of nicotine uptake. (Cancer Epidemiol Biomarkers Prev 2006;15(8):1495–501)

Introduction

The toxicity of cigarette smoke is determined by a complex set of product characteristics, including the tobacco blend and additives, as well as design features such as filter ventilation and paper porosity (1). To date, the primary means of testing cigarette toxicity has been to machine-smoke cigarettes according to a standard puffing regimen and to measure the constituents in the mainstream smoke. The protocol for machine smoking was adopted by the Federal Trade Commission (FTC) in 1967 and soon after by the International Organization for Standardization (ISO ref. 2). The FTC/ISO testing regimens are mandatory in many countries and form the basis for the tar and nicotine yields that are communicated to consumers via tobacco advertising and/or cigarette packs. ISO yields also serve as a regulatory limit in a number of jurisdictions, including the European Union, where brands that generate yields >30 mg tar, 1 mg nicotine, or 10 mg carbon monoxide (CO) are prohibited.

However, there are serious limitations to the FTC/ISO smoking regimen. The FTC/ISO puffing variables have been shown to systematically underestimate the size, frequency,

and velocity of puffs for most human smokers, including those who smoke “regular” yield, low-ventilation brands (3–6). In fact, the originators of the FTC/ISO method from the American Tobacco Company noted as early as 1936 that their method did not represent human smoking habits (7). The FTC/ISO method also did not account for compensatory smoking behavior, whereby human smokers regulate their intake by changing their puffing behavior to adjust for differences in nicotine delivery. Whereas human smokers increase the intensity of their puffing when smoking “low-yield” cigarettes, the FTC/ISO regimen smokes all cigarettes using the same puffing conditions (8–12). In addition, cigarette manufacturers have designed cigarettes to perform one way under machine testing, but to deliver much higher levels of nicotine and other smoke constituents in human hands (12,13). Filter ventilation—tiny perforations in cigarette filters that allow air to enter and dilute the cigarette smoke collected under machine smoking conditions—is the most prominent design element responsible for this discrepancy, but by no means the only one (12). As a consequence, the FTC/ISO machine yields bear little association with biological measures of uptake among human smokers (14–16).

There is an urgent need to revise the existing testing protocols. The Framework Convention on Tobacco Control—the first international public health treaty—includes provisions for testing and regulating cigarette emissions (17). Although there is strong consensus within the public health community that the ISO regimen is inadequate for the purposes of product regulation, there is little consensus regarding an alternative that could be recommended to the 126 countries that have ratified the Framework Convention on Tobacco Control to date (18–21). An ISO Working Group (ISO/TC 126/WG9) is currently reviewing options for a machine smoking regimen that is more representative of human smoking behavior.

Received 1/26/06; revised 5/19/06; accepted 5/16/06.

Grant support: U.S. National Cancer Institute (D.H.); Royal 4 Park Trust (G.T.F.); U.S. Tobacco Use Research Center, PIR CA11131, and R01 CA10240, the American Cancer Society, Health Canada, the Canadian Institutes for Health Research, and the Department of Health (G.A.G.).

The costs of publication of this article were defrayed in part by the payment of page charges. This article must therefore be hereby stated advertisement in accordance with U.S.C. Section 1734 solely to indicate this fact.

Note: This study was conducted at the University of Waterloo.

Requests for reprints: David Hammond, Department of Health Studies and Gerontology, University of Waterloo, 20 University Avenue West, Waterloo, Ontario, Canada N2L 2G1. E-mail: hammond@uwaterloo.ca

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0732-183X/06/15(8)-1495-07\$15.00

Cancer Epidemiol Biomarkers Prev 2006;15(8): August 2006

Protocol

Trial 1

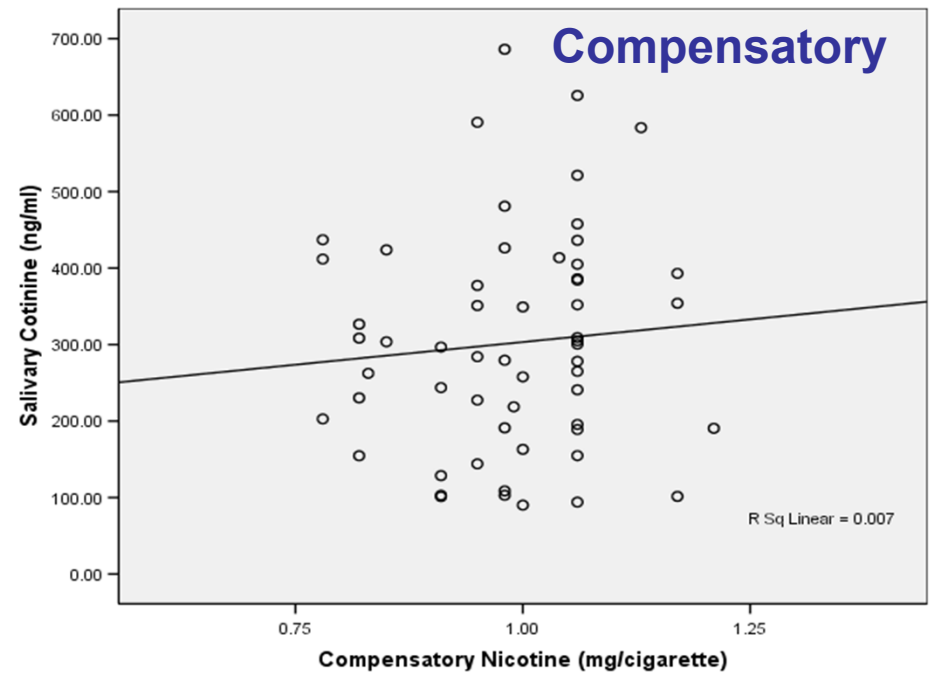
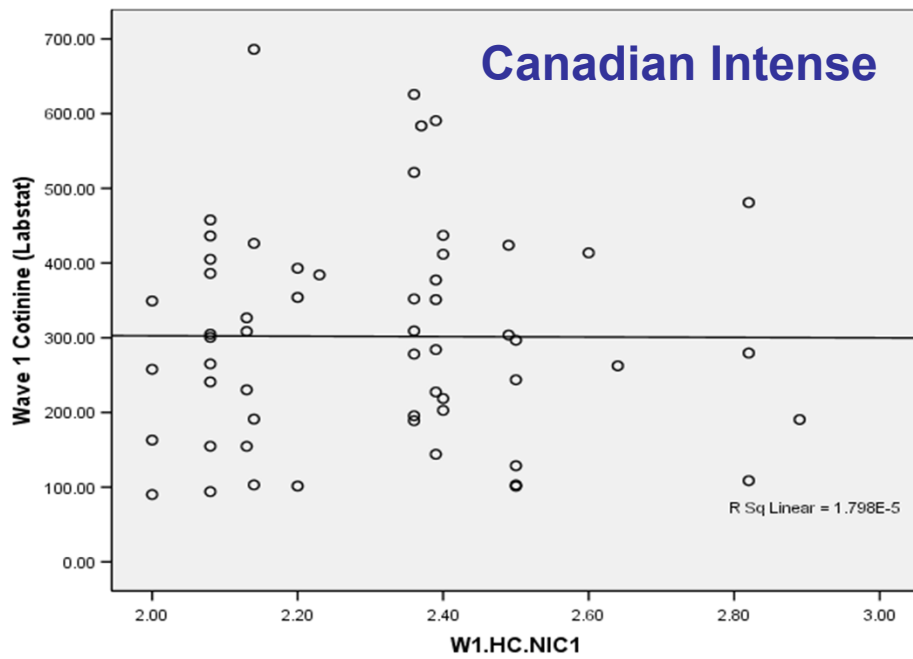
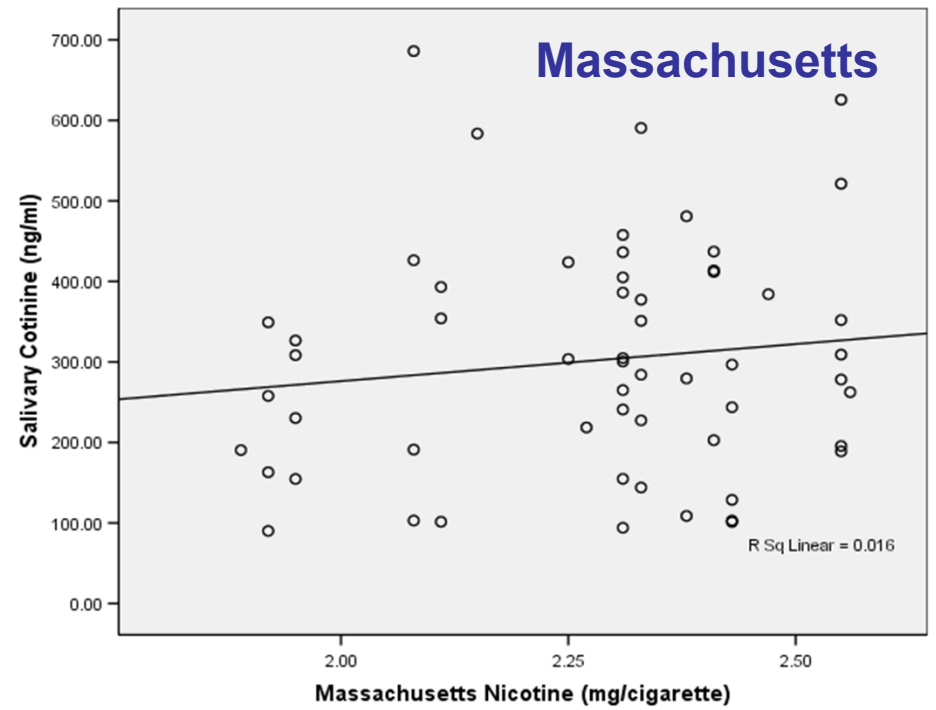
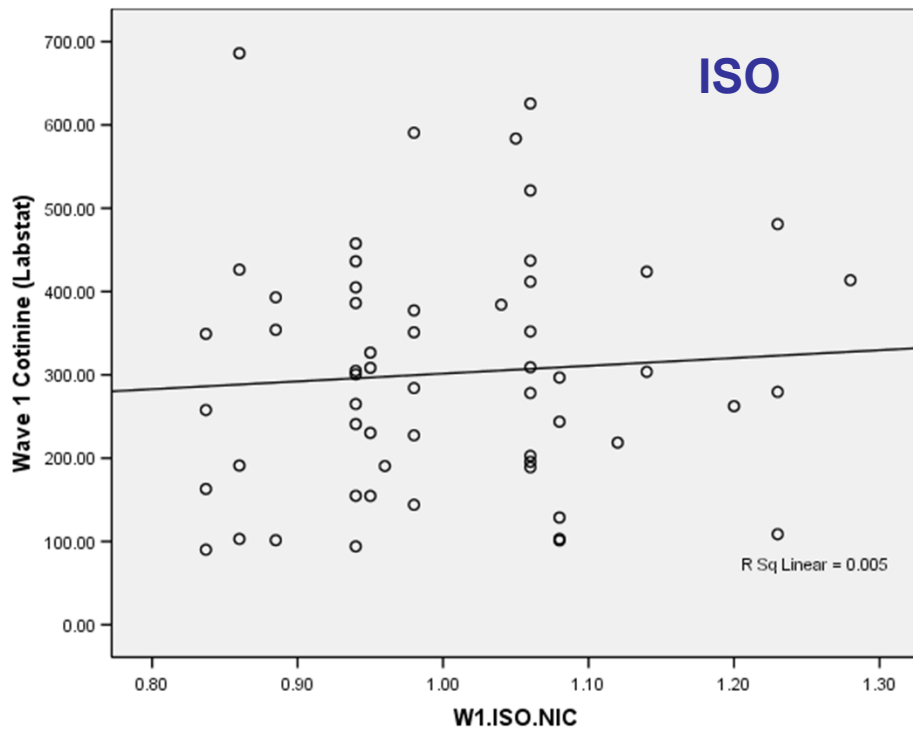
- Used the device for 4-5 consecutive days
- “Usual brand” (all between 0.8 and 1.3 ISO nicotine)
- Saliva sample collection (for cotinine analyses)

Trial 2

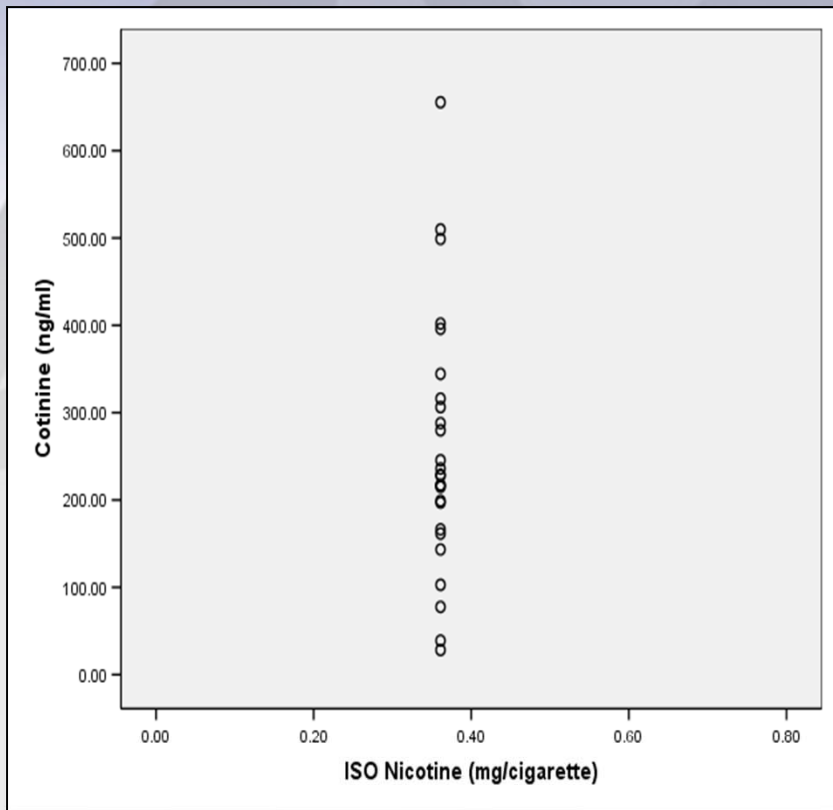
- Same protocol 1-week later

Trial 3

- 6 weeks later, half randomly assigned to “low-yield”
- 0.4 ISO mg of nicotine, 66% ventilated



Nicotine Uptake among smokers switched to Matinee Ultra Mild (n=26)



Summary

- Considerable variability in nicotine uptake within brands
- Very little variability in the “average” nicotine uptake across brands
- None of the ISO alternatives do a better job at capturing these fundamental patterns

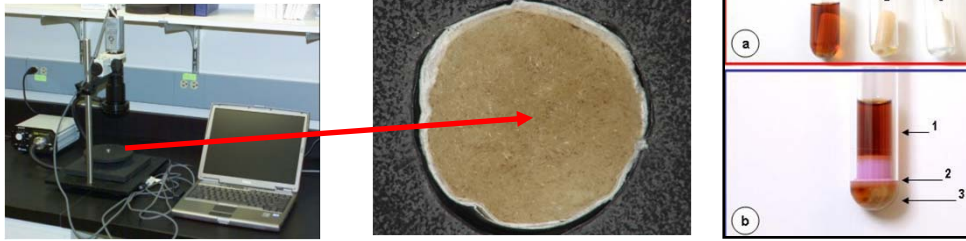
Implications

FCTC Article 11 says warnings and messages

...shall contain information on ~~relevant constituents and emissions.~~

Tobacco Research Laboratory

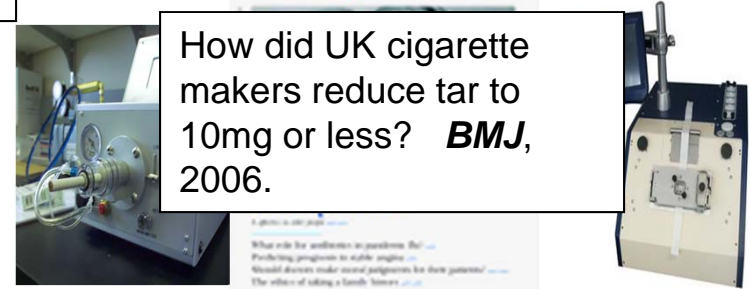
Digital image analysis of cigarette filter stains as an indicator of compensatory smoking. **CEBP**, 2006.



New ways to measure smoking behavior

BMJ

How did UK cigarette makers reduce tar to 10mg or less? **BMJ**, 2006.

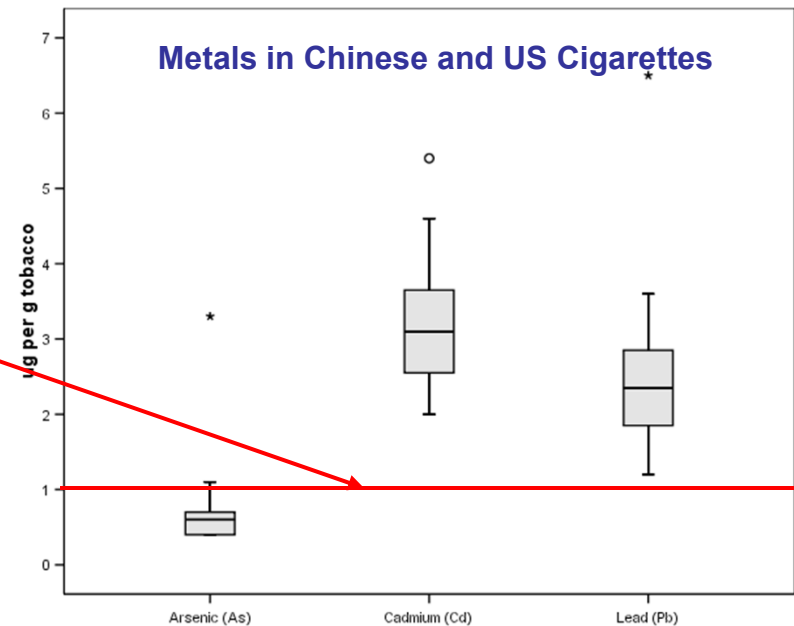


Cohort of over 200 brands from 19 countries, tracked over 4 years

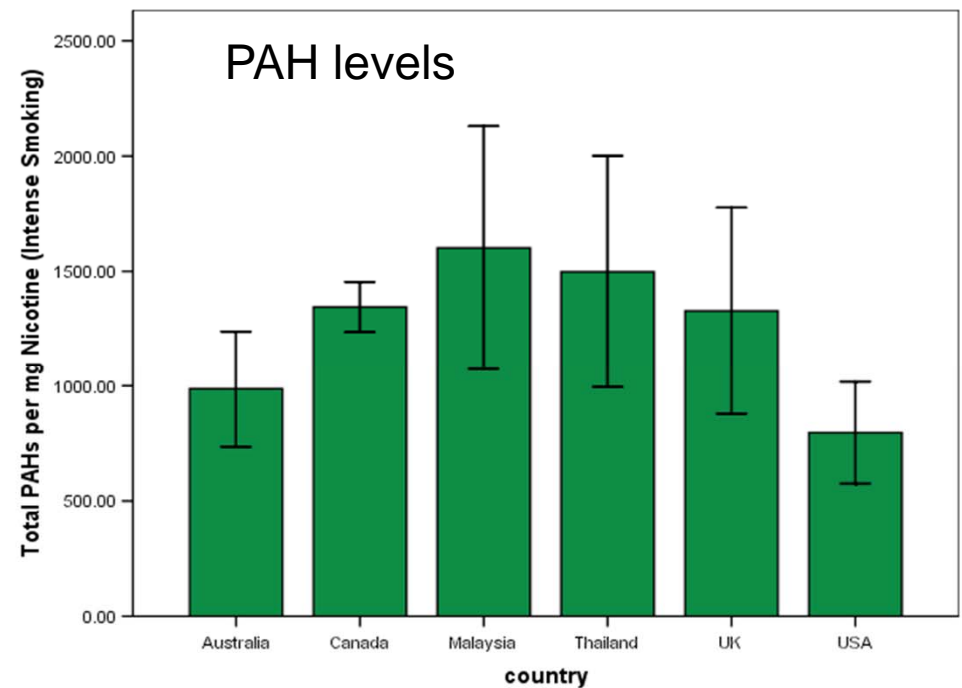
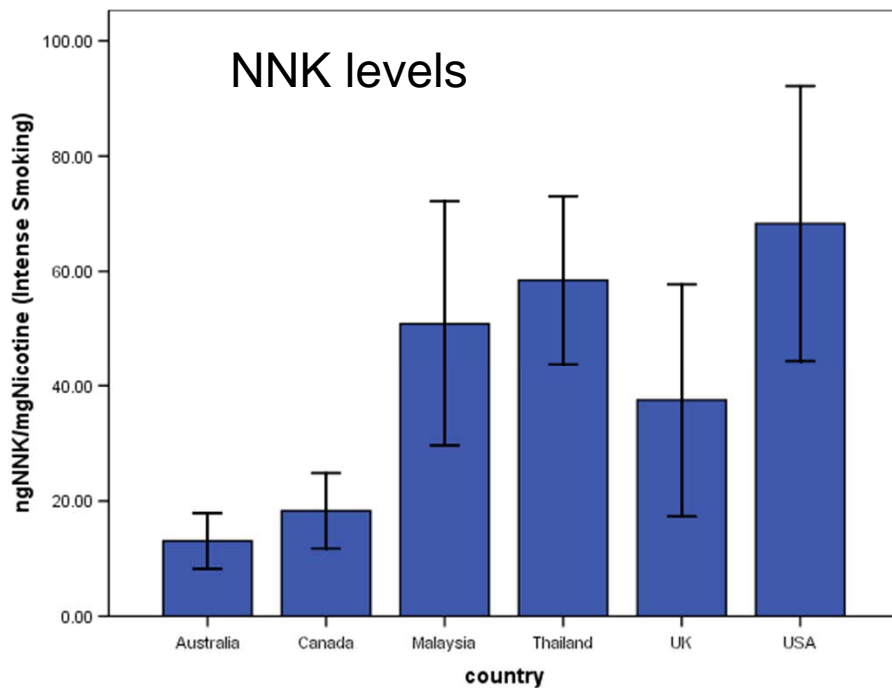


International Tobacco Products Repository

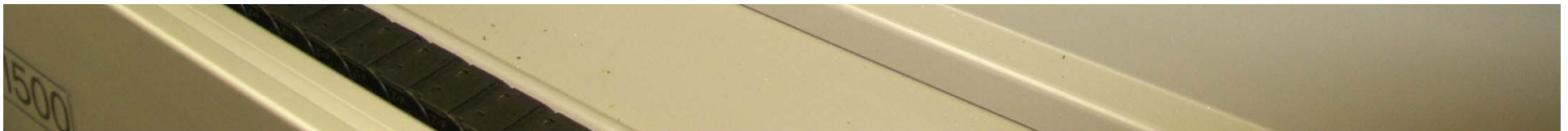
Product Design Characterization



Continuing CDC Collaboration

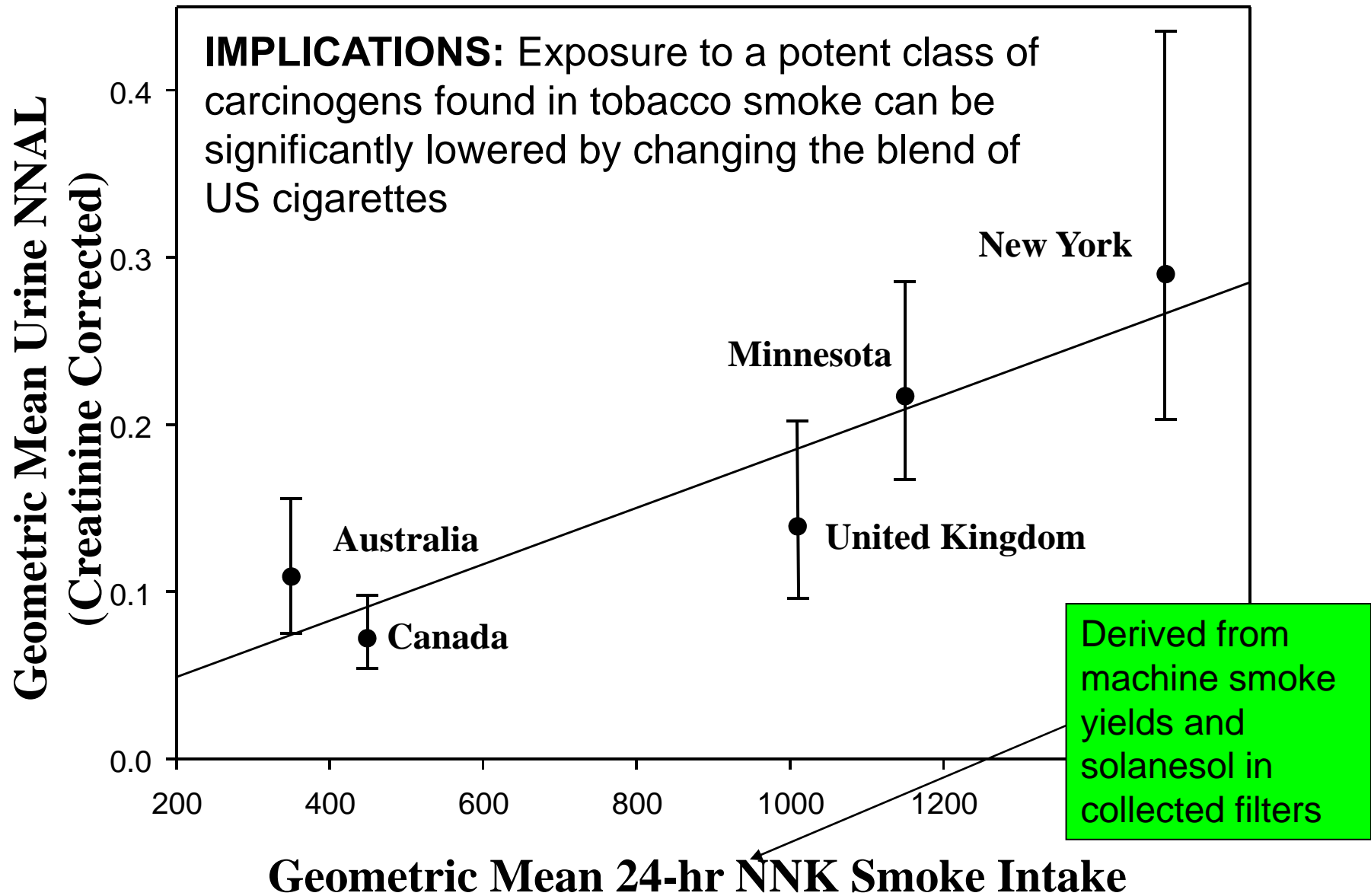


Emissions testing on leading brands of cigarettes from six ITC countries reveals variation in TSNAs and PAHs levels



TSNA Study Protocol

- Different countries have products with different levels of rod and smoke TSNA
- Would regular smokers of these brands differ in chemically-specific exposure biomarkers?
- Collaborative study with CDC and 5 sites in US (NY, MN), UK, Canada, and Australia
 - N=126 daily smokers of leading brands
 - Completed 2 lab visits and provided urine, saliva, and cigarette butt specimens
 - Usual brands tested for smoke TSNA by ISO and Canadian Intense methods



Ashley, O'Connor, Bernert, et al., in preparation.

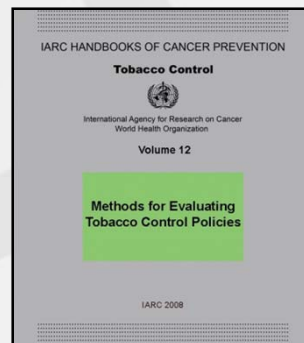
Translating tobacco control science to practice...



M measuring the Effectiveness of Tobacco Control
World Conference on Tobacco or Health
Pre-conference workshop • July 10—12 2006



itc conference
Effective Implementation of FCTC Policies
Pre-WCTOH Workshop - March 8, 2009
The International Tobacco Control Transdisciplinary Tobacco Use Research Center Conferences



<http://www.tobaccofreeair.org/>

TobaccoFreeAir.com
Training and resources for a smokefree world

Take the course
Course and air monitor support
Smokefree links
Global Irish Pub Study
The Heather Cross story... smokefree laws can save lives

Tools and Downloads
Take the Air Monitoring Course
Clean Air News
Home

Welcome to TobaccoFreeAir.com

Learn how to perform air monitor testing
Valid air monitoring has proved to have a profound effect on the creation, education and publicity around smoke-free policy initiatives.

This online course will help researchers who have been provided an SidePak air monitor through the Roswell Park cancer Institute to run air monitoring research in their country.

This online course will demonstrate how to:

- Setup and calibrate
- Operate and take measurements
- Download and access data

Take the course

As part of this study you are required to email your data files and observational notes to **Roswell Park** for additional analysis.

You will also have an opportunity to provide feedback regarding Air Monitor course. **We look forward to your comments.**



September 2008 Vol 17 Supplement 1

TOBACCO CONTROL

PRODUCT TESTING

Product Testing

tobaccocontrol.bmj.com

BMJ Journals



Translating tobacco control science to practice...

US Product warnings

<p>Canada 2000</p>  <p>Health Canada</p>	<p>Brazil 2002</p>  <p>MSK</p>	<p>Singapore 2004</p>  <p>MSK</p>	<p>Venezuela 2004</p>  <p>MSK</p>	<p>Thailand 2005</p>  <p>MSK</p>	
<p>Australia 2006</p>  <p>MSK</p>	<p>Uruguay 2006</p>  <p>MSK</p>	<p>European Union Pictorial Warnings (Optional)</p>			 <p>MSK</p>
		 <p>MSK</p>		 <p>MSK</p>	

The rest of the world

Translating tobacco control science to practice...

Labeling: Pictures Trump Text on Cigarette Warnings - New York Times



February 13, 2007
Vital Signs

Labeling: Pictures Trump Text on Cigarette Warnings

By NICHOLAS BAKALAR

Do health warnings on cigarette graphics and have recently been

The researchers analyzed data. The survey, to be published in several questions to determine

Canadian cigarettes carry a warning package, and 16 versions are covered 6 percent of the front 16 larger rotating warnings. of the back of the package. In the pack only, and they have

The Canadian design was the States package was least effective with 30 percent of smokers in

The revised package in Britain

"The two main ingredients in communicate health risks," said health studies at the University words alone cannot."



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LIFESTYLE / Health

Picture warnings will 'make smokers give up'

(Daily Mail)
Updated: 2007-02-07 17:07

Bigger and more graphic health warnings on cigarette packets would make smokers quit, according to research.

A study of different warnings on packets around the world revealed pictures of diseased lung and congested arteries would spur more people to give up.

Proposals are now being put together to add images to cigarette packets in Britain. Research from Cancer Research UK found prominent warnings were more likely to be read but they must also be regular or smokers became inured to them.

Professor Gerard Hastings, of the Institute of Social Marketing at the University of Stirling, said health warnings work and can save lives as a result. But this study shows that the design and the message affects how well it does its job.

Warnings on packets in four countries were analysed. Images used in Canada had the most messages on the side of packets in America the least. The UK recently increased the size of put them on the front of packets which raised their effectiveness and motivated more people.

But picture warnings had a great impact on making smokers think about the health implications more likely to make them put down the cigarette they were about to smoke.

Almost 15,000 smokers were surveyed over four years on their awareness of the health message changes in understanding of the risk, their intention or motivation to quit and behaviour change.

Jean King, director of tobacco control at Cancer Research UK, urged ministers to bring in what she called the "hardest hitting" images.

BBC NEWS | Health | Picture smoking warnings 'best'



Picture smoking warnings 'best'

Pictorial health warnings on cigarette packets are more likely to encourage smokers to quit, a study says.

The University of Washington-led research also found large and regularly updated text warnings were more likely to be noticed than smaller ones.

Researchers looked at different approaches taken in four countries - Canada, the US, the UK and Australia - analysing the impact on 15,000 smokers.

The UK currently uses text warnings, but picture alerts start this year.

However, when the study, published in the American Journal of Preventive Medicine, started, the UK was only using smaller warnings.

This allowed researchers to monitor the impact of changing the nature of warnings.

Canada already uses graphic images, such as text saying smoking causes impotence accompanied by a drooping cigarette, on packets.

In Australia, large text warnings - just below the internationally recommended standards of 30% coverage of the cigarette packet - were introduced eight years before the study was carried out.

Small text warnings have been used in the US since 1984.

Smoke Free After



Conclusions

- Good public health practice, the same as clinical medicine, demands rigorous evaluation to guide the adoption of strong evidenced-based interventions
- The ITC Project is conducting rigorous evaluation of FCTC policies and has quickly become the primary source of data for FCTC protocols adopted by countries
- The ITC Project is synergistic with other global tobacco control initiatives
 - WHO's treaty monitoring
 - CDC's Global Tobacco Surveillance System
 - Policy advocacy funded by the Bloomberg/Gates Foundations
- Research on FCTC policy effects will help inform how the FDA ultimately regulates tobacco