



International Tobacco Control
Policy Evaluation Project

The ITC Nicotine Product Conceptual Model: A Framework for Understanding Transitions Among Cigarettes, E-Cigarettes, and Other Nicotine Products and the Impact of Policies on Those Transitions

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E-cigarettes
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Commission

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for Research & Innovation

Presenter's disclosures



- Paid expert witness or consultant for governments defending their country's policies or regulations in litigation: Australia (plain packaging, WTO); Uruguay (labeling policies, bilateral investment treaty)
- Member, Scientific Advisory Board on Vaping Products, Health Canada (2017-2020)
- Member of the Expert Group for Article 9 (Regulation of the contents of tobacco products) and Article 10 (Regulation of tobacco product disclosures) of the WHO FCTC (2019)
- No funding or support from companies that manufacture tobacco or nicotine products.
- No funding from pharmaceutical companies

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



Canada



United States



Australia



United Kingdom



Greece



Vietnam



Ireland



Thailand



Malaysia



Republic of Korea



Hungary



China



Uruguay



Mexico



New Zealand



Poland



France



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Netherlands



Bangladesh



Romania



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Mauritius



Bhutan



India



Spain



Zambia



Kenya



Abu Dhabi



Japan



Israel

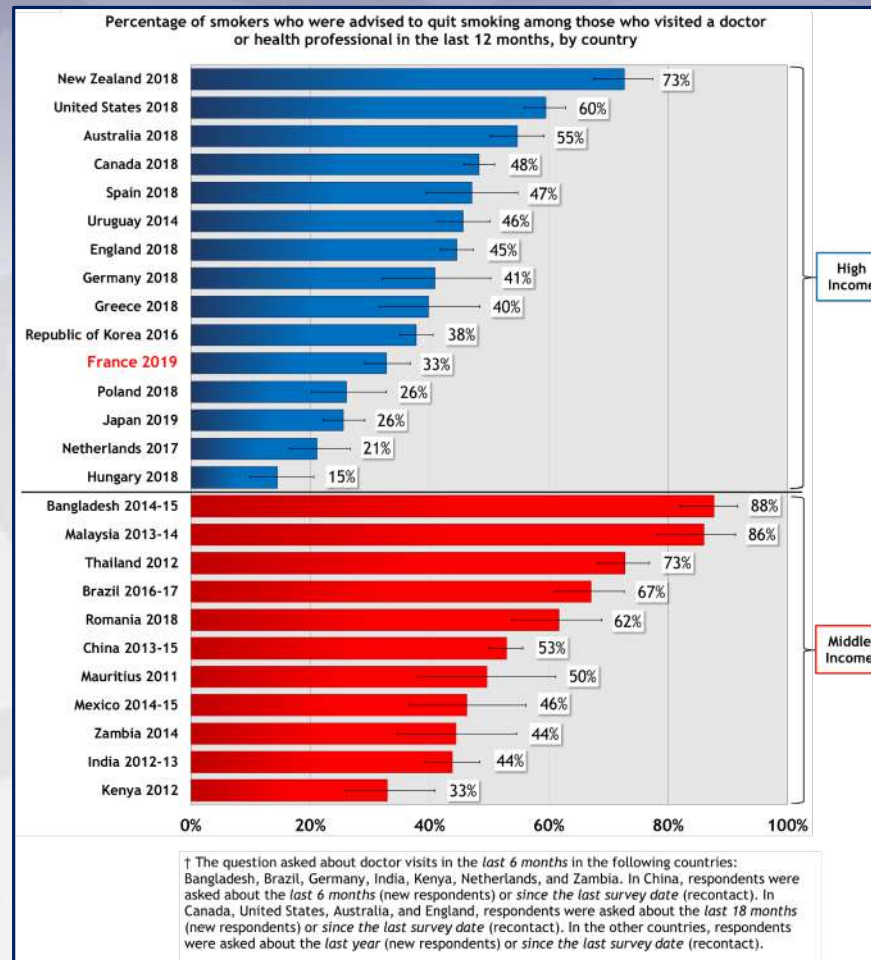
- Created in 2002 (prior to adoption of FCTC)
- 31 countries: >1/2 of world's population and >2/3 of world's tobacco users
- Merged methods and measures of behavioural sciences/psychology with sampling and methods of surveillance systems
- First-ever international cohort study of tobacco

ITC France Survey



- ITC France National Cohort Survey:
3 waves conducted: 2006-07, 2008, 2012
- New cohort wave conducted in 2009
- ITC 2019 France Survey: Conducted by
CATI (Oct 31 to Dec 17, 2019)
- N = 2,212 (1,679 Smokers and
533 Non-Smokers)

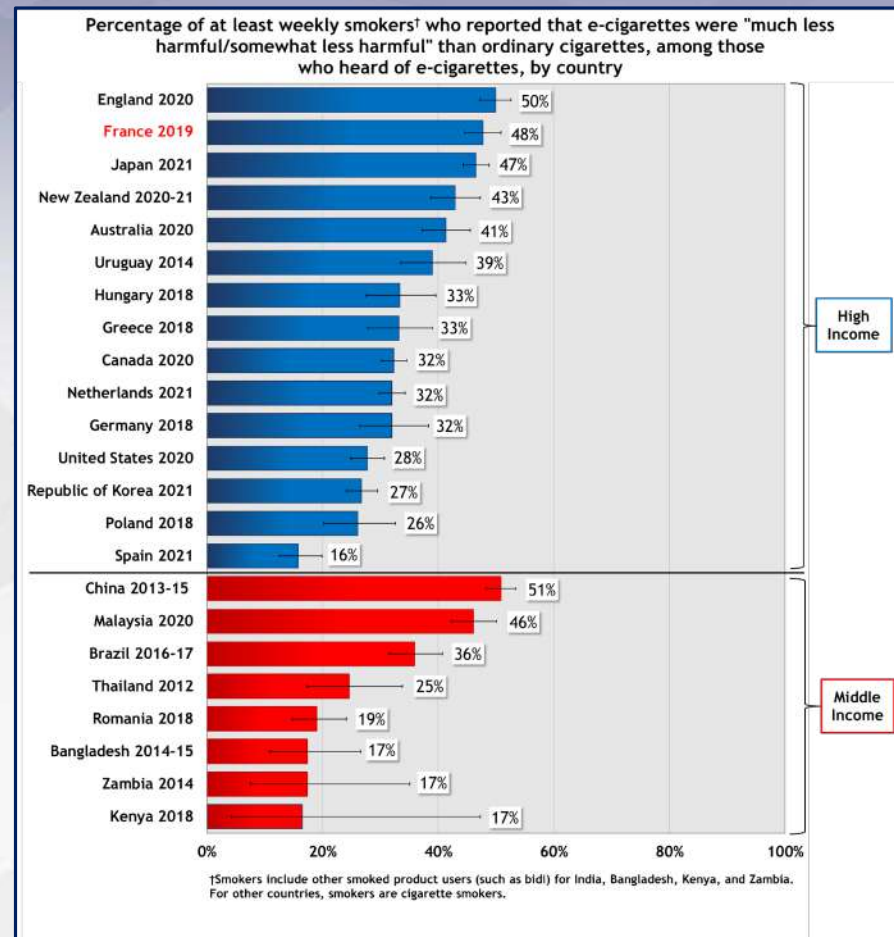
% of smokers reporting that their physician advised them to quit smoking in the last 12 months



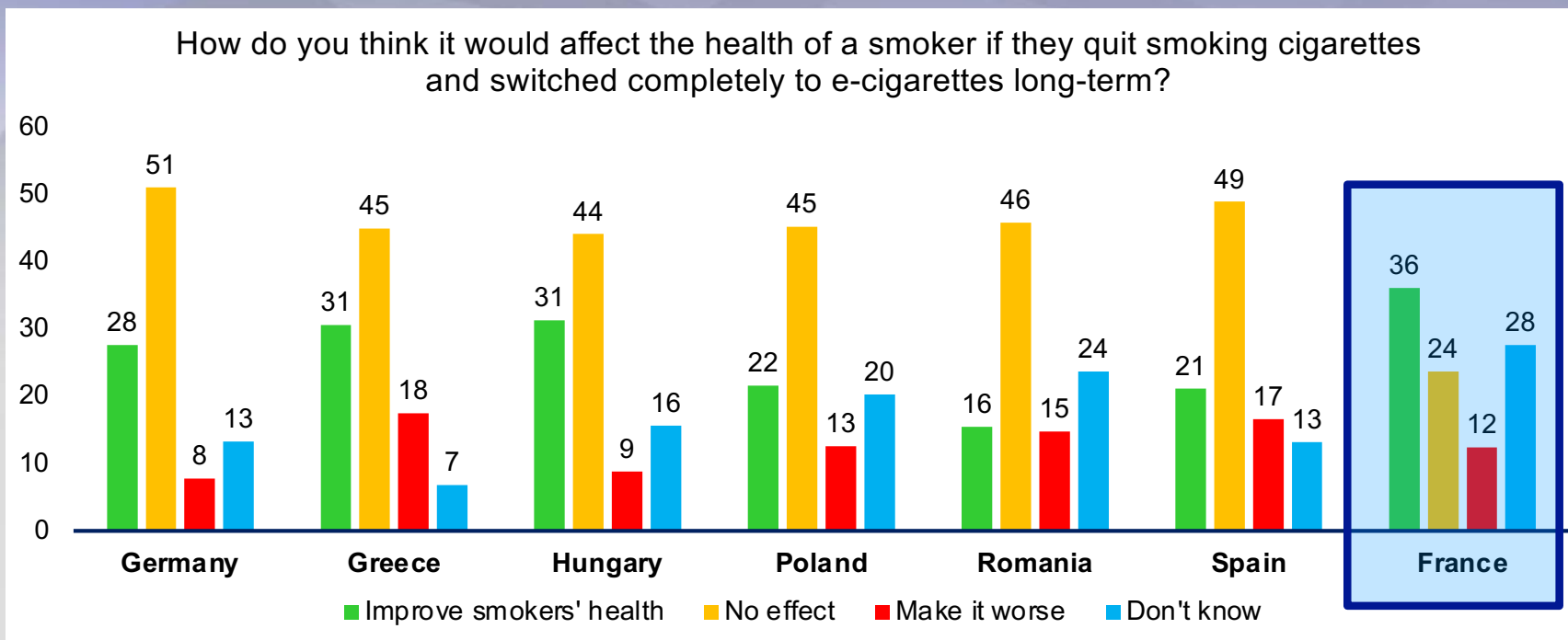
- In France: only 1/3 of smokers reported that their physician advised them to quit smoking in the last year.
- 11th among 15 ITC high-income countries

% believing ECs are less harmful in 23 ITC countries: 15 high-income and 8 low/middle-income

Recent comprehensive reviews of the available scientific evidence by the US National Academy of Sciences, Engineering, and Medicine (NASEM), Public Health England / OHID, and the Royal College of Physicians have concluded that although e-cigarettes contain harmful constituents, overall, they are less harmful than combustible cigarettes.

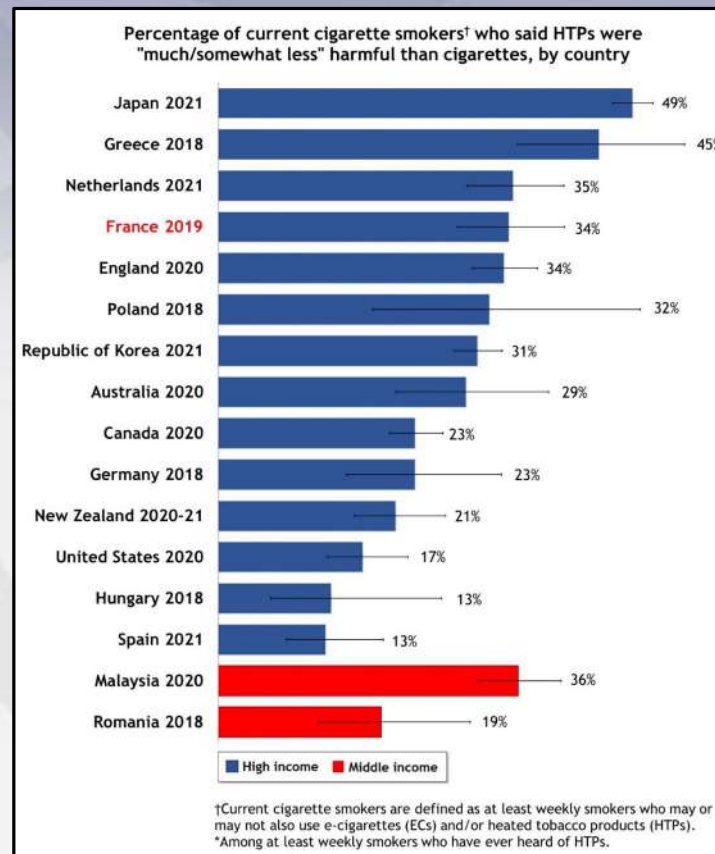


What would happen to the health of a smoker if they transitioned completely to e-cigarettes?

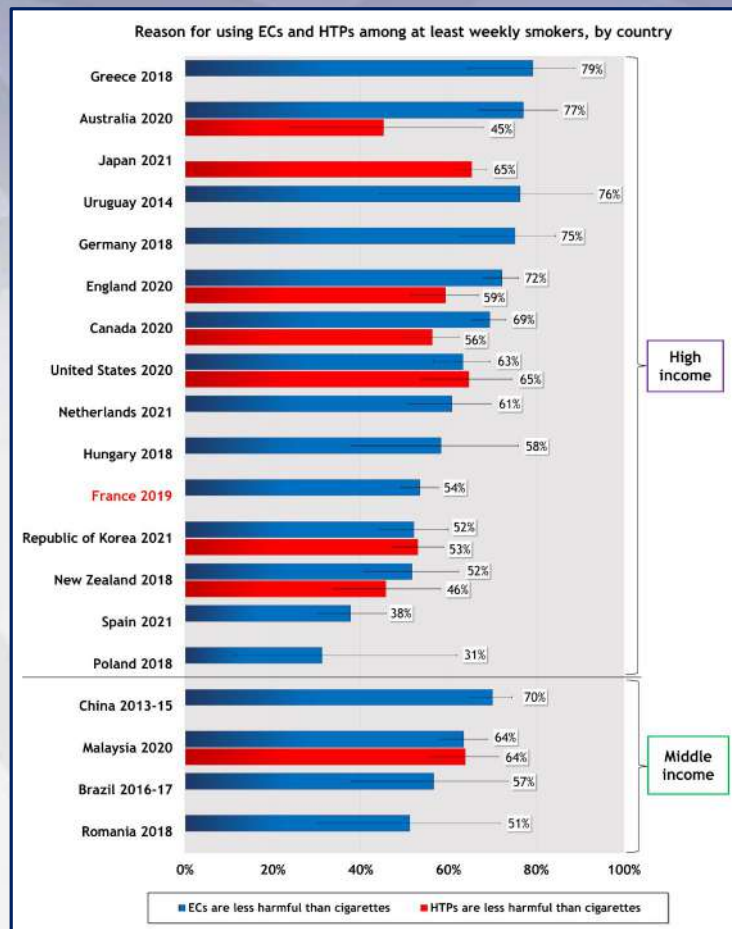


- Nearly half of smokers believe that there would be no effect (except France at 36%); 1/2 to 2/3 believe that there would be no effect or that switching completely to vaping would actually **worsen** health (except France: 36%)
- Belief that completely switching from cigs to ECs improves health: highest in France (36%) lowest in Romania (16%)

16 ITC countries: % of cigarette smokers who believe that HTPs are less harmful than cigarettes.



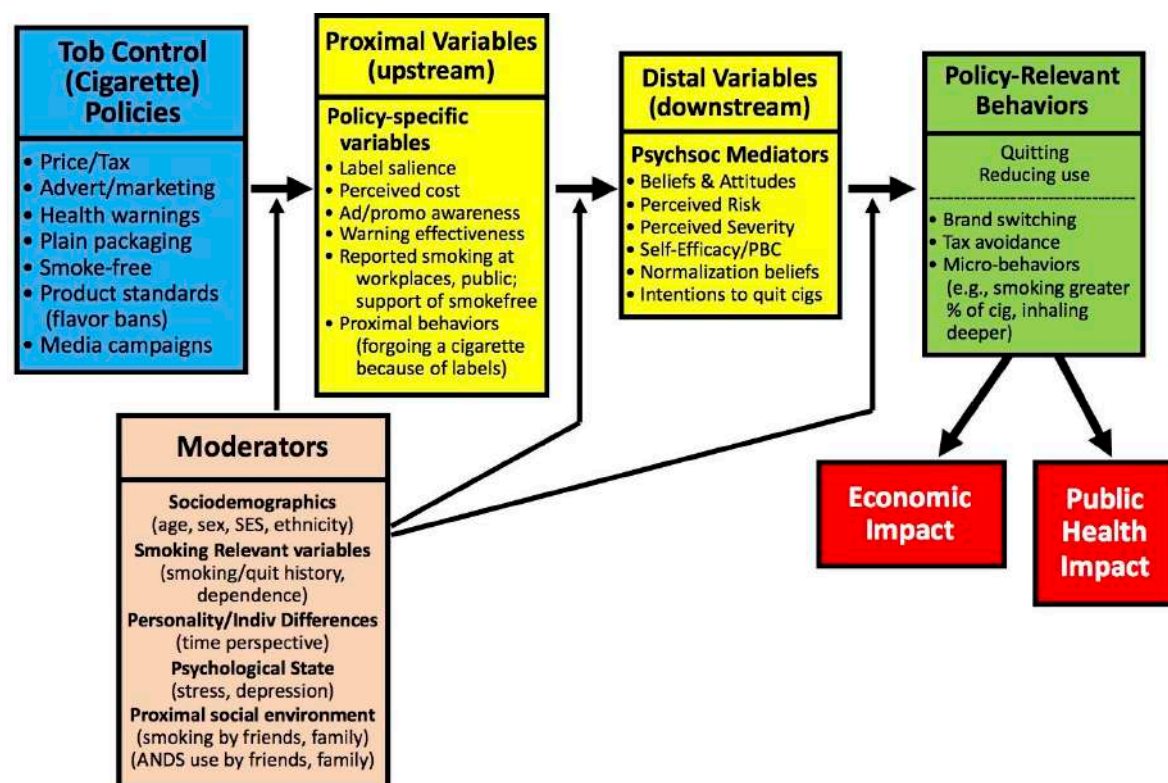
19 Countries: % who are using ECs or HTPs because they believe them to be less harmful than cigarettes





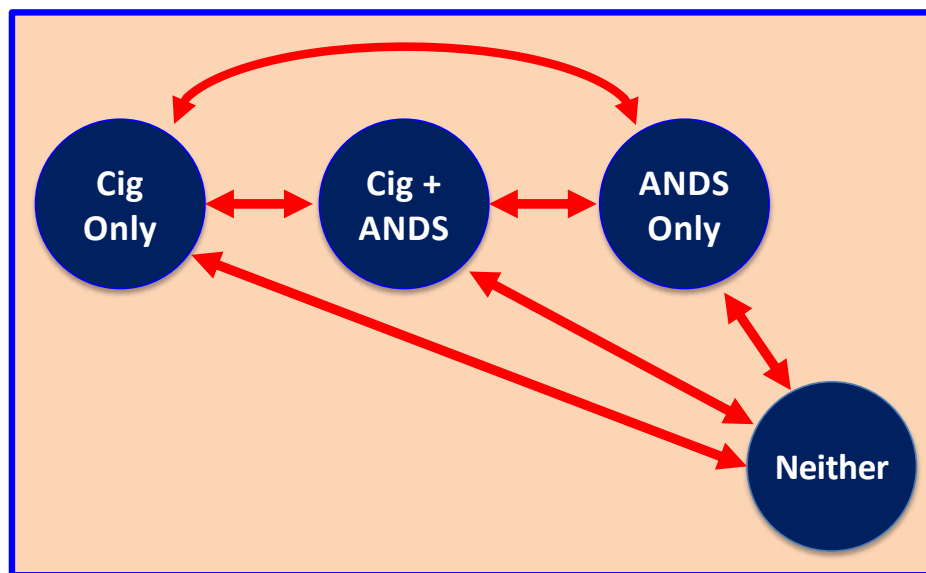
The ITC Conceptual Model for Transitions Between Cigarettes and Other Nicotine Products

ITC Conceptual Model: For Cigarettes



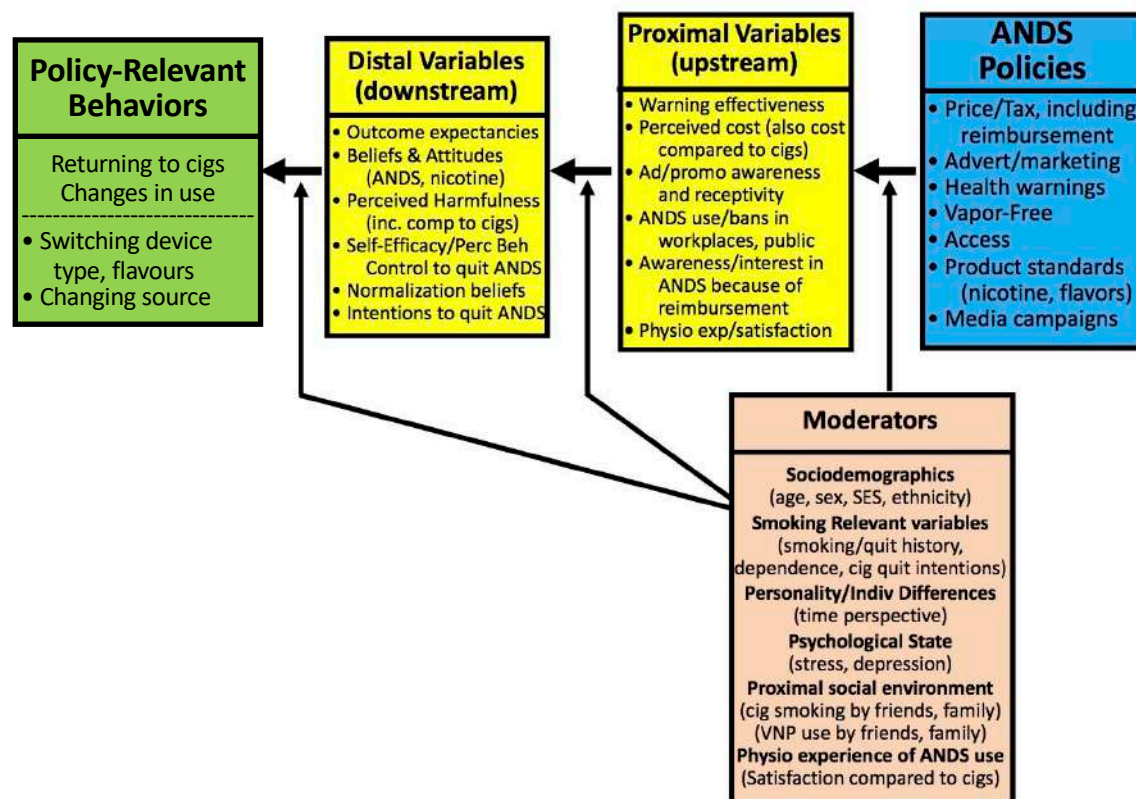
- Model developed from key theories in social/health psychology
- Includes key psychosocial variables that are known to be related to current behaviour and future behaviour.
- This model has been used to create/select all of the measures included in the ITC surveys
- Policy evaluation: examining not just whether policies have an impact on behaviour, but also **how and why** policies have their impact on behaviour.

Transition Arena: Cigarettes and Alternative Products



ITC Conceptual Model: For ANDS (E-cigs or HTPs)

- The same key psychosocial variables also apply for understanding why people use ECs or HTPs, etc.
- Thus, the ITC Conceptual Model is equally applicable for ANDS
- In our countries where we are also focusing on ANDS use, the survey includes questions on ANDS that mirror questions on cigarettes.
- This allows for a direct comparison of the factors that are related to using any of the tobacco/nicotine products in that country's market.

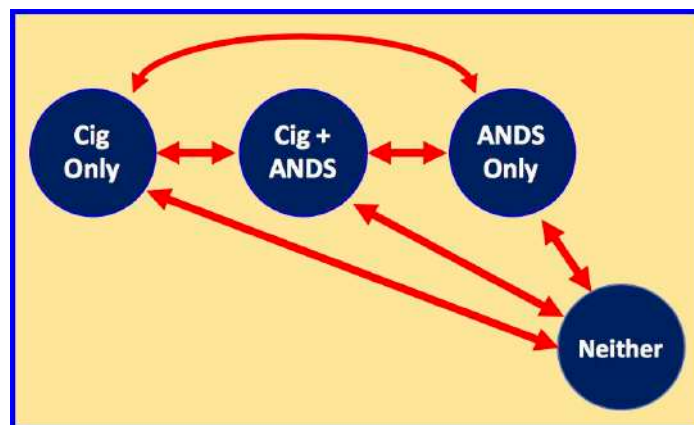


Cross-price elasticity and its generalization



- Cross-price elasticity: measures the extent to which changes in price of one product affects the demand of another product that is a substitute. Indeed, the magnitude of the cross-price elasticity defines the extent to which the other product is a substitute.
- Generalization: with two products that are (potential) substitutes, ANY policy/regulation that affects the demand of one product may have an impact on the demand of the other product.
- Examples: restrictions in access, flavours, advertising bans
- Generalization: **cross-policy elasticity (effects)**

Nicotine products (cigs, ECs, HTPs, et al.) and their policy impacts on the transition arena



TC (Cigarette) Policies

Restrictive cigarette policies

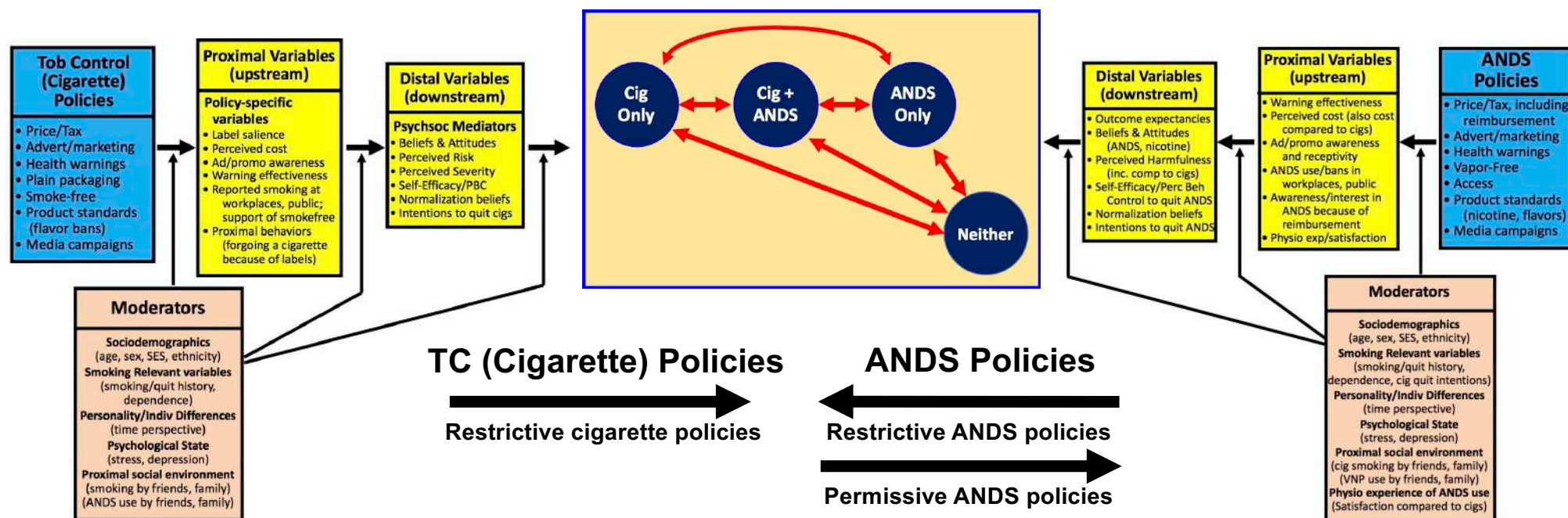
ANDS Policies

Restrictive ANDS policies

Permissive ANDS policies

- Cigarette/tobacco control policies all push consumers away from cigarettes.
- But 2 kinds of ANDS policies:
 - **Restrictive policies** (bans, access restrictions, flavour bans) may PUSH consumers away from VNPs (and maybe toward cigs);
 - **Permissive policies** (differential taxation) may PULL consumers toward VNPs

ITC Conceptual Model: extended to examine the impact of policies on cigarettes and ANDS (ECs, HTPs)



Because cigarettes and e-cigarettes are substitutable goods, it is essential to examine the impact of BOTH cigarette policies **AND** e-cigarette policies to examine their impact on use of e-cigarettes, and transitions to/from cigarettes and e-cigarettes.

ITC 7-Country Nicotine Product Adult (NPA) Survey

ITC International Nicotine Product Adult Survey in 7 Countries:
United States, Canada, England, Australia, Japan, Republic of Korea, New Zealand

		Countries Requesting NIH Support			Countries Supported Entirely By Other Funding Sources			
Description		United States	Canada	England	Australia	Japan	Korea	New Zealand
Sample Size		2,150 adults (18+)	2,150 adults (18+)	2,300 adults (18+)	1,500 adults (18+)	4,500 adults (20+)	4,700 adults (19+)	1,600 adults (18+) (incl. Indigenous)
User Group	Cigarette smoker	X	X	X	X	X	X	X
	Recent ex-smoker	X	X	X	X	X	X	X
	NVP user	X	X	X	X	X	X	X
	NVP+Cigarette dual	X	X	X	X	X	X	X
	HTP user	X	X	X	X	X	X	X
	HTP+Cigarette dual	X	X	X	X	X	X	X
	Never/Non-user	X	X	X	X	X	X	X
Web Survey Length (mins)		45	45	45	45	30	35	40
Waves completed to date		3	3	3	3	3	1	3
Fieldwork dates of completed waves		Jul-Nov 2016	Jul-Nov 2016	Jul-Nov 2016	Jul-Nov 2016	Feb-Mar 2018	Jun 2020	Aug 2016-Apr 2017
		Feb-Jul 2018	Feb-Jul 2018	Feb-Jul 2018	Feb-Jul 2018	Dec 2018-Jan 2019		Jun-Dec 2018
		Apr-Jun 2020	Apr-Jun 2020	Apr-Jun 2020	Apr-Jun 2020	May-Jun 2020		Nov 2020-Feb 2021
Future Survey Waves		3	3	3	3	6	6	4
Fieldwork dates of future waves						Sep-Nov 2021	Sep-Nov 2021	Jun-Aug 2021 Feb-Apr 2022
		Apr-Jul 2022	Apr-Jul 2022	Apr-Jul 2022	Apr-Jul 2022	Sep-Nov 2022	Sep-Nov 2022	Oct-Nov 2022
						Sep-Nov 2023	Sep-Nov 2023	Sep-Nov 2023
		Feb-May 2024	Feb-May 2024	Feb-May 2024	Feb-May 2024	Sep-Nov 2024	Sep-Nov 2024	
						Sep-Nov 2025	Sep-Nov 2025	
		Feb-May 2026	Feb-May 2026	Feb-May 2026	Feb-May 2026	Sep-Nov 2026	Sep-Nov 2026	
Current Funding Sources		Current P01	Current P01 + CIHR	Current P01	Current NHMRC	Current CIHR	Current Korean Health Prom Inst	Current NZ Health Research Council
Future Funding Sources		P01 Renewal + In-kind CIHR	P01 Renewal + In-kind CIHR	P01 Renewal + In-kind CIHR	NHMRC Renewal (pending)	CIHR	Korean Health Prom Inst	NZ Health Research Council
Project 3 ETM sub-study		Yes	Yes	Yes	Yes	No	No	No

Yellow shaded cells: User group quotas included in the sampling design; **Green shaded cells:** User group quotas not included in sampling design, but included within user groups that have quotas (e.g., in the US, NVP-cigarette duals will be among respondents sampled from the cigarette smoker group and the NVP user group). In all countries, the screening procedure allows us to recruit all ANDS (e.g., in the US we will recruit HTP users even though they are not allocated a quota due to low prevalence). **Pink shaded cells:** Not recruited, but in subsequent waves, respondents from other user groups will become non-users, and thus these will be retained (users who become non-users are of special interest, e.g., cigarette smokers who quit are categorized as non-users). **CIHR:** Canadian Institutes of Health Research; **NHMRC:** National Health and Medical Research Council.

Cross-policy effects: Restrictive EC policies



Restrictive EC policies

Most studies have been of this kind, examining the impact of variation or changes in EC tax rates, advertising restrictions, minimum age of legal sale.

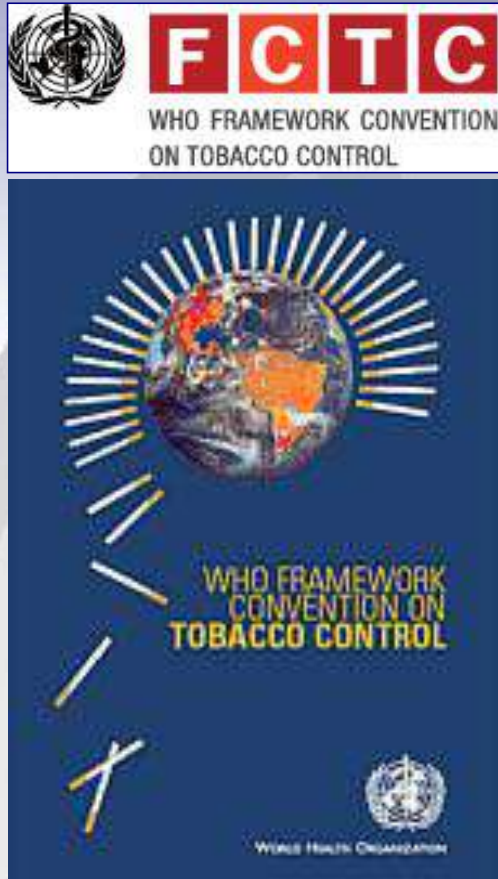
- Tuchman (2019): Analysis of 2010-15 U.S. data: e-cigarette advertising reduces demand for cigarettes. Proposed e-cig advertising ban estimated to increase cig sales by 1.0%

Permissive EC policies

Very few examples of such policies, but would predict that such policies might have an effect on reducing demand for cigarettes. (Per Tuchman)

What about restrictive cigarette policies?

WHO Framework Convention on Tobacco Control



- First-ever WHO treaty (2005); ratified by 181 countries (90% of world's population)
- Parties obligated to implement key policies such as:
 - Higher tobacco taxes
 - Comprehensive smoke-free laws
 - Large graphic warnings,
 - Advertising/marketing bans
 - Support for cessation
 - Product regulation: reduce appeal, addictiveness

The FCTC is likely the greatest disease prevention initiative in history



Has the FCTC made a difference?

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;

Assess impact on implementation AND effectiveness

- Global evidence review of 17 FCTC articles (ITC Project)
- Country missions to 12 FCTC Parties
- Other external reports
- Report presented at COP7 (2016)

FCTC Impact Assessment Supplement in Tobacco Control



Foreword by the Secretariat of the WHO Framework Convention on Tobacco Control

Vera Luiza da Costa e Silva

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

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

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

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

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

Stella Aguinaga Bialous

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

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

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

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

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

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

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

Thomas F McInerney

Impact of the WHO FCTC on non-cigarette tobacco products

Ghazi S Zaatari, Asma Bazzi

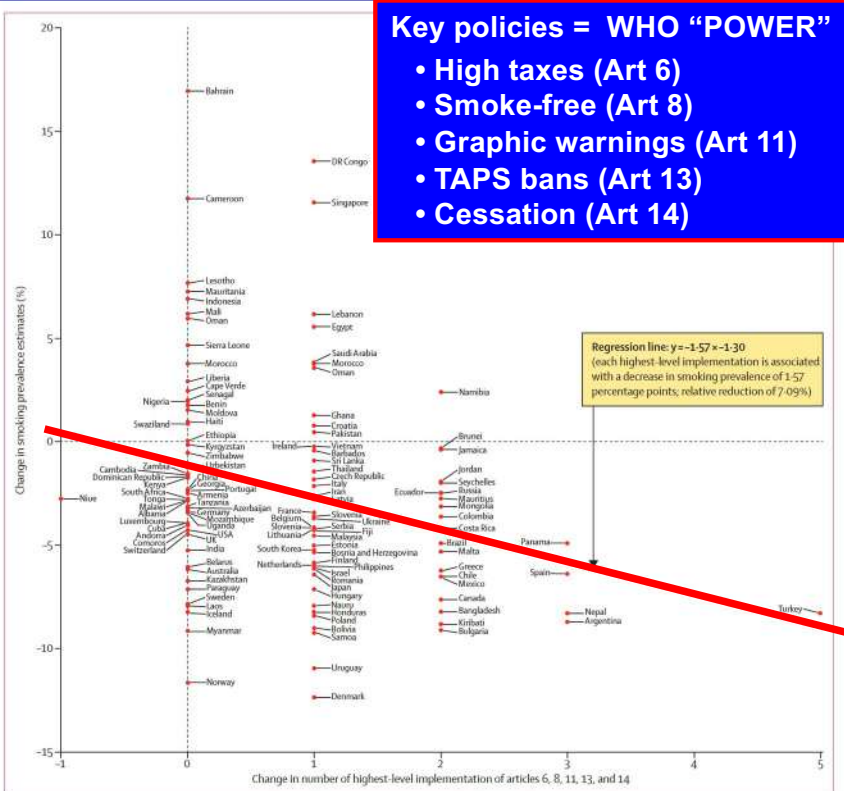
Impact of the WHO FCTC on tobacco control: perspectives from stakeholders in 12 countries

Lorraine Craig,¹ Geoffrey T Fong,^{1,2,3} Janet Chung-Hall,¹ Pekka Puska,⁴ for the WHO FCTC Impact Assessment Expert Group

The FCTC works...to reduce smoking substantially IF implemented...

Key policies = WHO "POWER"

- High taxes (Art 6)
- Smoke-free (Art 8)
- Graphic warnings (Art 11)
- TAPS bans (Art 13)
- Cessation (Art 14)



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.–Lancet Public Health (2017)

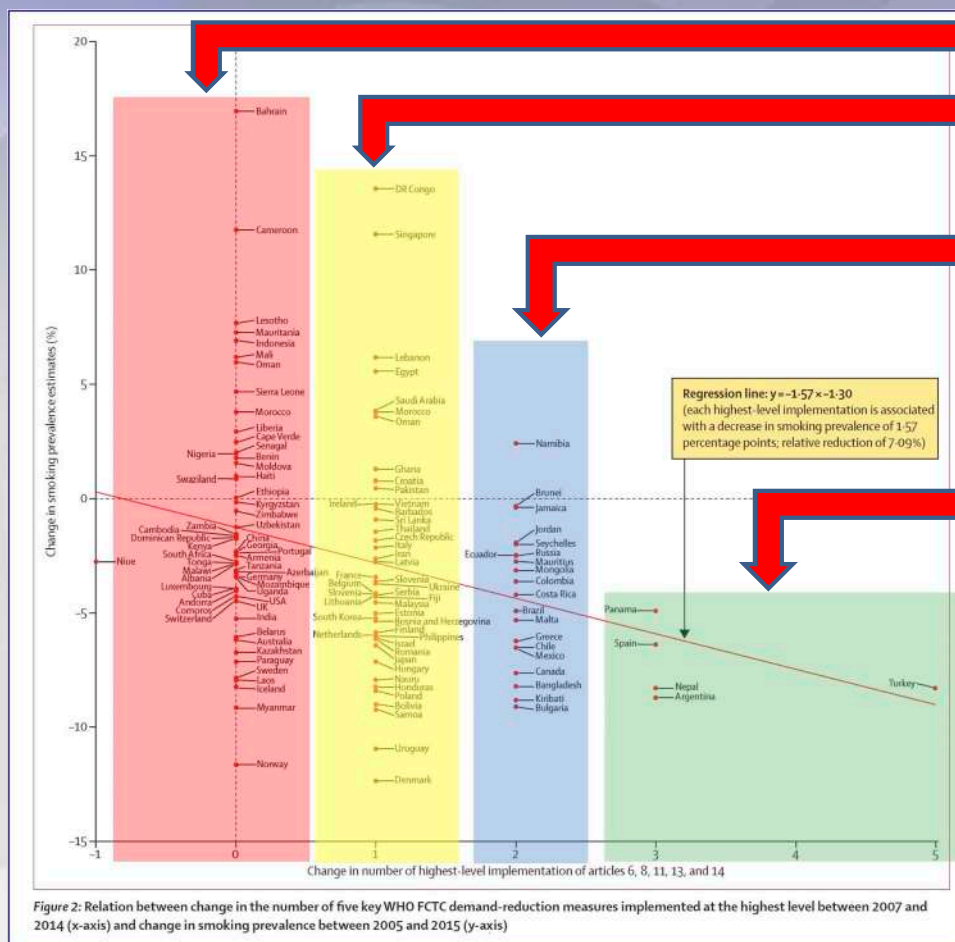
- Number of POWER policies implemented in the first decade of the treaty
- Change in smoking prevalence in first decade of treaty
- Strong dose-response effect: Each policy implemented **at the highest level** associated with reduction of 7% relative decrease of smoking prevalence

The WHO FCTC works...

...if key FCTC policies are implemented at a strong level.

But there's a problem...

...the FCTC implementation has been very slow



55 countries: ZERO of 5 policies

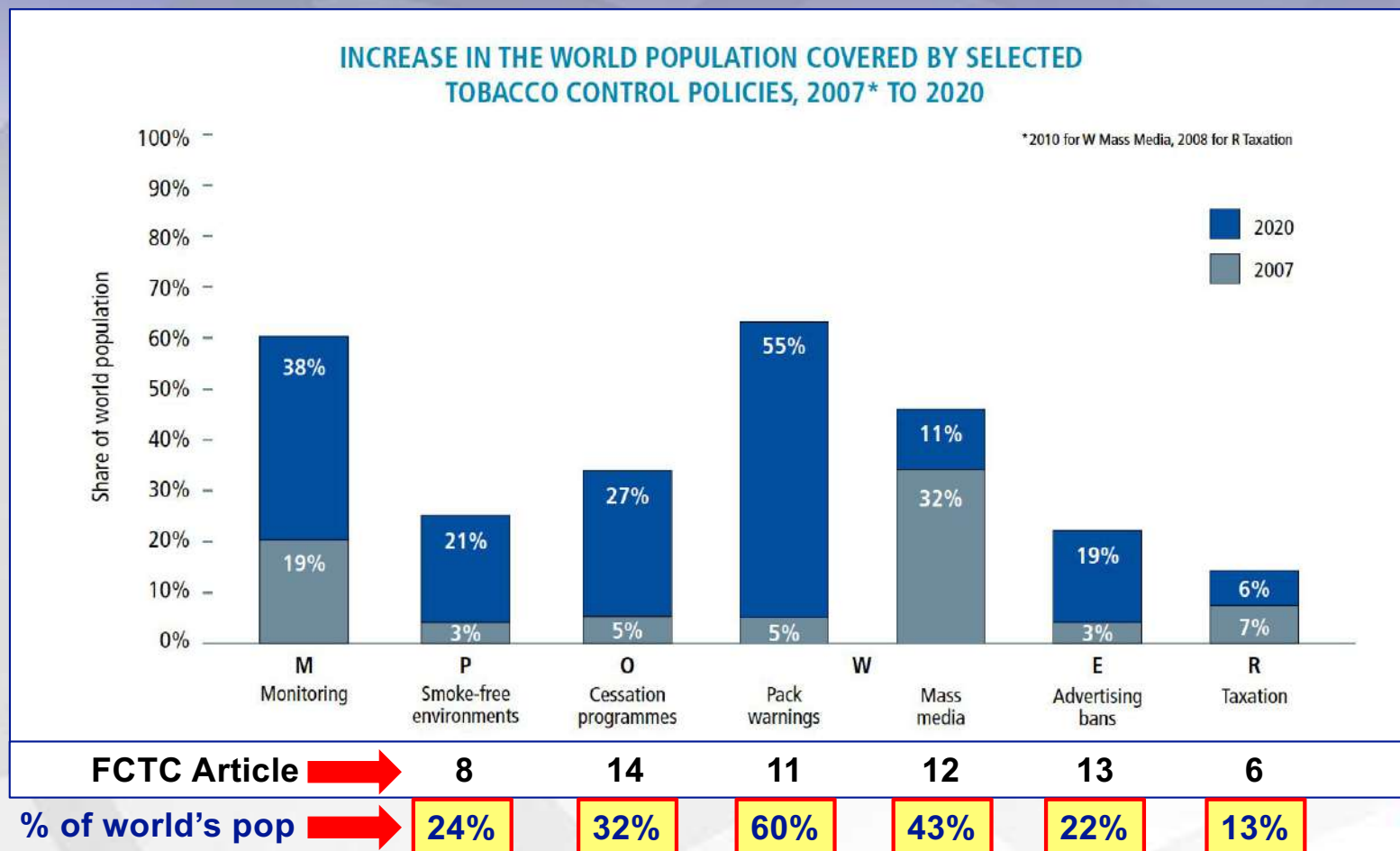
45 countries: ONLY 1 of the 5 policies

20 countries: ONLY 2 of the 5 policies

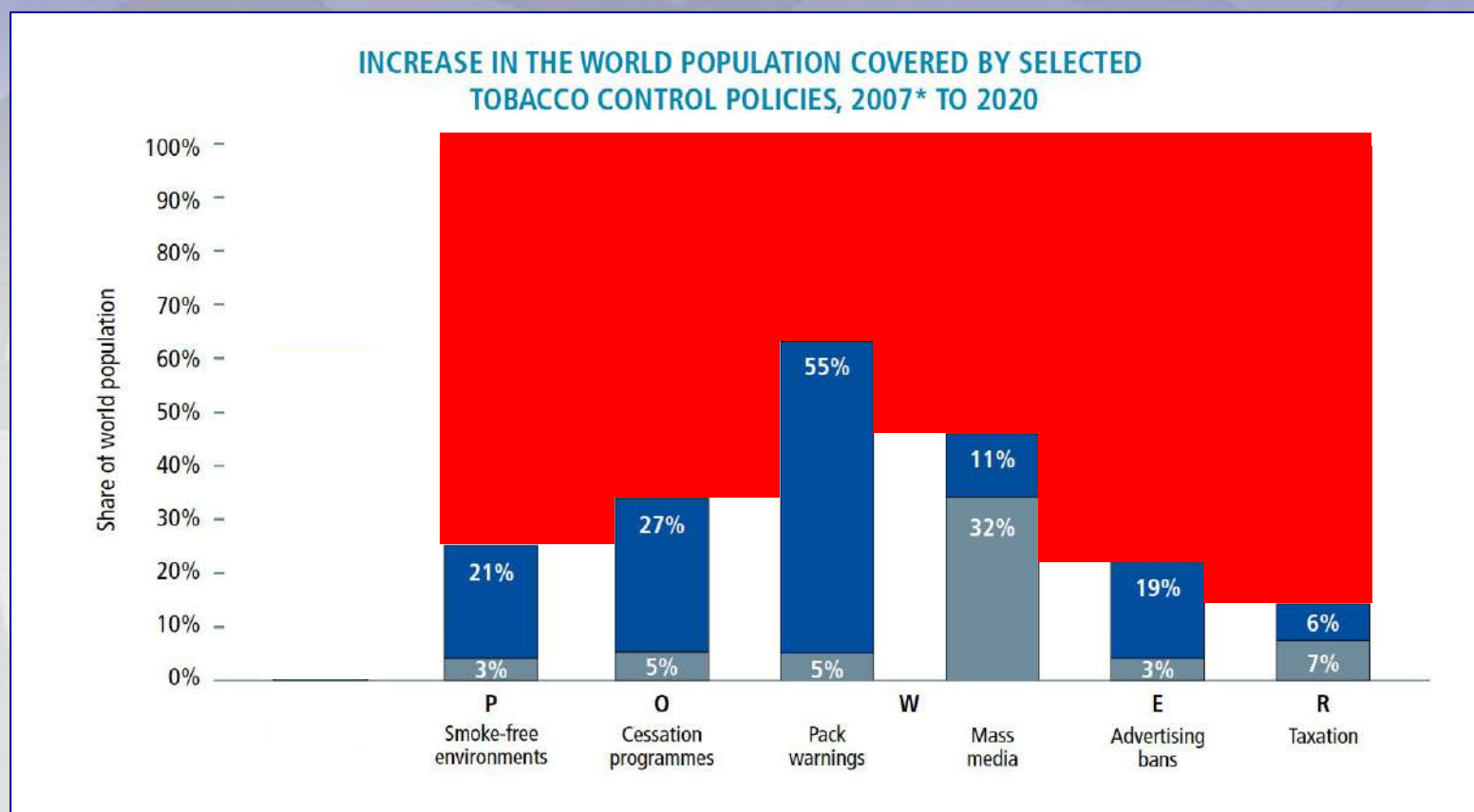
Only 5 countries implemented 3 or more of the 5 policies

Very slow implementation:
The average country implemented only 1.04 of the 5 key FCTC/POWER policies at the highest level

Progress in implementation of key demand-reduction measures (2007-2020)



The gap in FCTC implementation



The FCTC COP has recognized the importance of accelerating implementation of the treaty



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

2.2.3. Promote research that is relevant to WHO FCTC implementation, in particular priorities set out in the Strategy, in accordance with Article 20.



GLOBAL STRATEGY TO **ACCELERATE** TOBACCO CONTROL

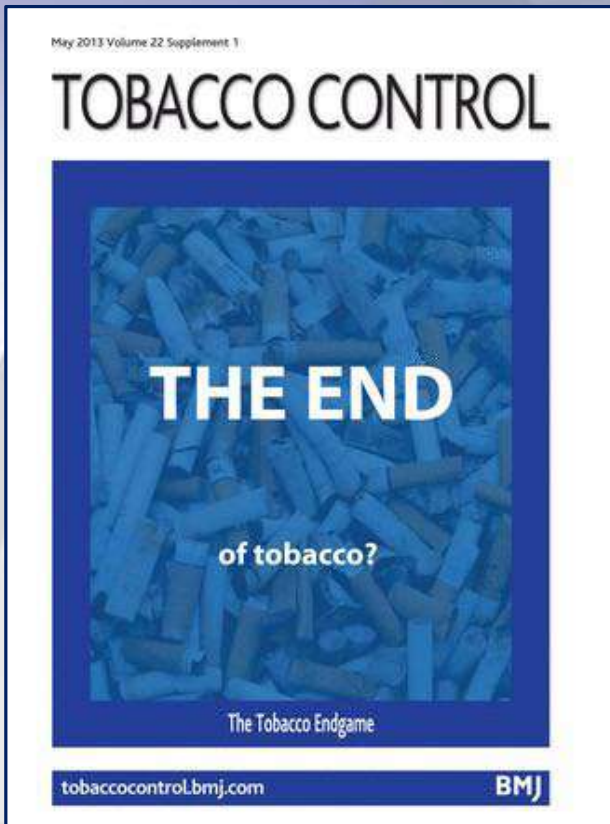
Advancing sustainable development
through the implementation
of the **WHO FCTC 2019 - 2025**





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

Tobacco Endgame Initiatives



“Initiatives designed to change/eliminate permanently the structural, political and social dynamics that sustain the tobacco epidemic, in order to achieve within a specific time an endpoint for the tobacco epidemic.”

Incremental vs. disruptive measures

Incremental Measures

- **Strong(er) implementation of FCTC policies (POWER measures):**
 - Increasing taxes
 - Active and sustained media campaigns
 - Total smoke-free laws
- **Extensions of FCTC policy domains:**
 - Plain packaging
 - T21

(Potentially) Disruptive Measures

- **Strong supply-side measures:**
 - Reduce number of retailers
 - Restrict type of retail
- **Product regulation designed to reduce appeal and addiction**
 - Ban flavours
 - Ban filters
 - Limit nicotine to very low levels in combustible products

Linkage to broader objectives

- Inequalities, environment, human rights

Bridging Endgame proposals to the FCTC: Article 2.1

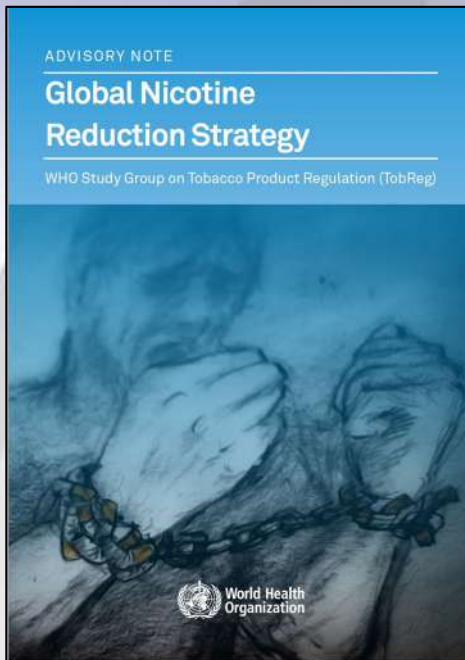
*"In order to better protect human health,
Parties are encouraged to implement measures beyond those required by this Convention and its protocols, and
nothing in these instruments shall prevent a Party from imposing stricter requirements that are consistent with their provisions and are in accordance with international law."*

Very low nicotine cigarettes (VLNCs)

WHO/TobReg (2015)

US FDA: June 21, 2022

FDA: Apelberg et al. NEJM (2018)

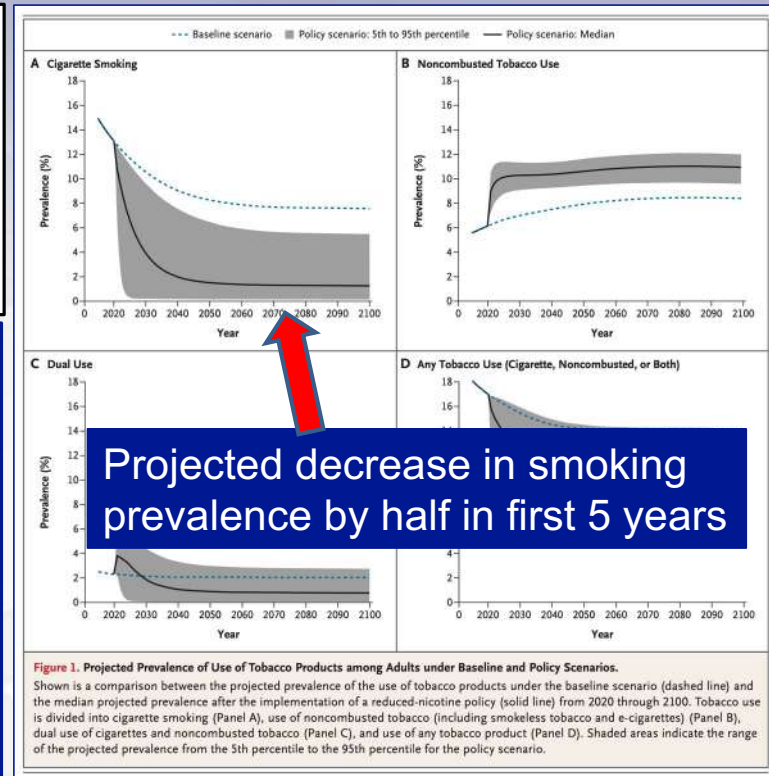


FDA NEWS RELEASE

FDA Announces Plans for Proposed Rule to Reduce Addictiveness of Cigarettes and Other Combusted Tobacco Products

Potential Rule Would Propose to Establish a Maximum Level of Nicotine in Cigarettes with the Goal of Reducing Youth Use, Addiction and Death

- **Clinical trials** show impact of VLNCs to promote reduction and cessation without compensation
- **Simulation modeling:** huge potential in reducing smoking among smokers AND preventing uptake and progression to regular smoking



New Zealand: Proposals for Smoke-free Aotearoa 2025 Action Plan



Recent events and future steps

2021: Review of submissions + advice to Minister
2021: Final action plan and Cabinet considerations
2022: Legislation and implementation

1. Strengthen the tobacco control system

- Māori governance
- Community action for SF2025
- Research, evaluation and monitoring

2. Reduce Availability

- Limit number of retail outlets and store types
- ~~Retailer licensing~~
- Smoke-free generation policy

3. Reduce Addictiveness and appeal

- Mandated VLNCs
- Prohibit filters
- Prohibit design innovations

4. ~~Reduce Affordability~~

- ~~Minimum prices~~

5. Intensify current initiatives

- Enhanced cessation support (priority populations)
- Increased mass media campaigns

Implications



- The FCTC has been shown to reduce smoking, but poor implementation has limited its impact. The COP's Strategic Plan calls for support to **strengthen and accelerate implementation of the FCTC**.
- Very strong potential for cross-policy impact. FCTC measures to reduce demand for cigarettes is likely to increase demand for alternative nicotine products.
- Recent policies (menthol bans) demonstrate the enormous impact of population-level measures. The Canadian menthol ban led to 7.3% of menthol smokers quitting. Effect size x reach: if the proposed FDA ban on menthol cigarettes is implemented, projected impact = 1.33M US smokers quitting
- Endgame proposals are gaining momentum. Very low nicotine cigarettes is a particularly promising regulatory measure.

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- Additional support to GTF is provided by the Ontario Institute for Cancer Research, Ontario, Canada.

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P01 CA200512



Canadian Institutes of Health Research
FDN-148477



Ontario Institute for Cancer Research
Senior Investigator Award (2007-2022)

ITC Project Research Organizations



ITC Project Research Support



