

Potential Health Benefits of a Nicotine Standard

Tobacco Control Forum
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The Role of Addictive Properties in Tobacco Use

- Tobacco use is the leading preventable cause of premature death and disease in Canada. An important factor in the continued use of tobacco products is nicotine, which is a highly addictive substance.
- The nicotine-mediated addictiveness of tobacco is powerful.
 - One-third of those who try smoking become daily smokers¹
- The pharmacologic and behavioral processes that determine tobacco addiction are similar to those that determine addiction to drugs such as heroin and cocaine.²
- Reducing tobacco's addictive properties could potentially help in reducing the number of people who use tobacco.

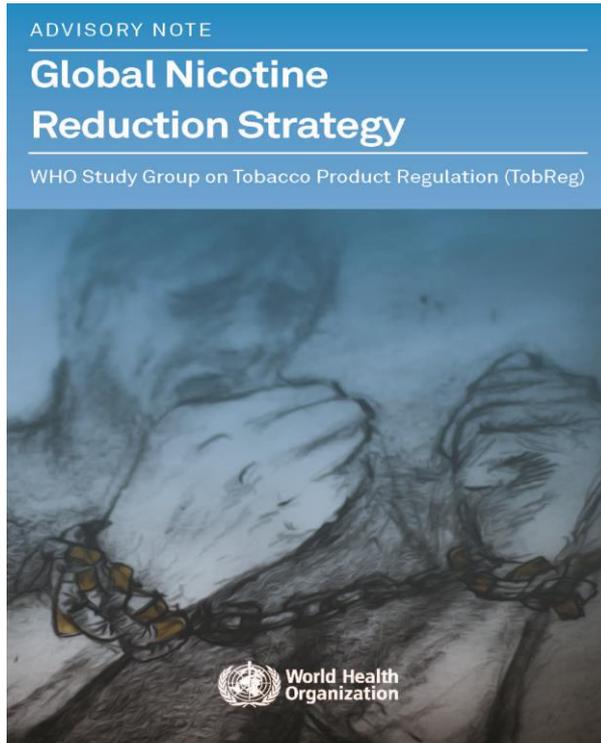
1. DHHS. (1994). *Preventing tobacco use among young people: A Report of the Surgeon General*.

2. DHHS (1988). *How Tobacco Smoke Causes Disease: A Report of the Surgeon General*

Background: Tobacco Addictiveness Reduction

- **TOBACCO ADDICTIVENESS REDUCTION** refers to product requirements (e.g. standards) to minimize the addictive properties of tobacco products with the objectives of:
 - Preventing/reducing initiation
 - Increasing cessation
 - Decreasing consumption
- **NICOTINE REDUCTION** in tobacco products is currently thought to be the most practical means of reducing their addictiveness.
 - Nicotine in tobacco can be reduced before products are manufactured:
 - Tobacco plants can be genetically modified to produce less nicotine
 - Nicotine can be extracted (similar to the decaffeination of coffee)

Recent Drivers for Tobacco Addictiveness Reduction



- As a party to the World Health Organization Framework Convention on Tobacco Control (FCTC), Canada has an obligation to research, propose, develop and implement policies to prevent and reduce nicotine addiction¹
- In November 2016, the seventh session of the FCTC Conference of Parties (COP) agreed to convene a meeting with a range of experts and relevant stakeholders to consider and report to COP8 on issues related to addictiveness reduction²

1. WHO Framework Convention on Tobacco Control (see Article 5)
<http://apps.who.int/iris/bitstream/10665/42811/1/9241591013.pdf>

2. Decision FCTC/COP7(14): Further development of the partial guidelines for implementation of Articles 9 and 10 of the WHO FCTC.
[http://www.who.int/fctc/cop/cop7/FCTC_COP7\(14\)_EN.pdf](http://www.who.int/fctc/cop/cop7/FCTC_COP7(14)_EN.pdf)

US FDA Nicotine Framework

- US Food and Drug Administration (along with the National Institutes of Health) have made addictiveness reduction a research priority.¹
- A Nicotine-Focused Framework for Public Health
 - “The regulatory framework for reducing harm from tobacco must include nicotine — the chemical responsible for addiction to tobacco products — as a centerpiece.”
- In March 2018, US FDA issued an advanced notice of proposed rulemaking (ANPRM) seeking public comment on development of a potential nicotine product standard that would lower nicotine to a minimally or non-addictive level. The ANPRM is open for public comment through June 14, 2018.

1 National Institutes of Health, Office of Disease Prevention. <https://prevention.nih.gov/tobacco-regulatory-science-program/research-priorities>

2 The New England Journal of Medicine published on August 16, 2017, at NEJM.org <https://www.nejm.org/doi/full/10.1056/NEJMp1707409>

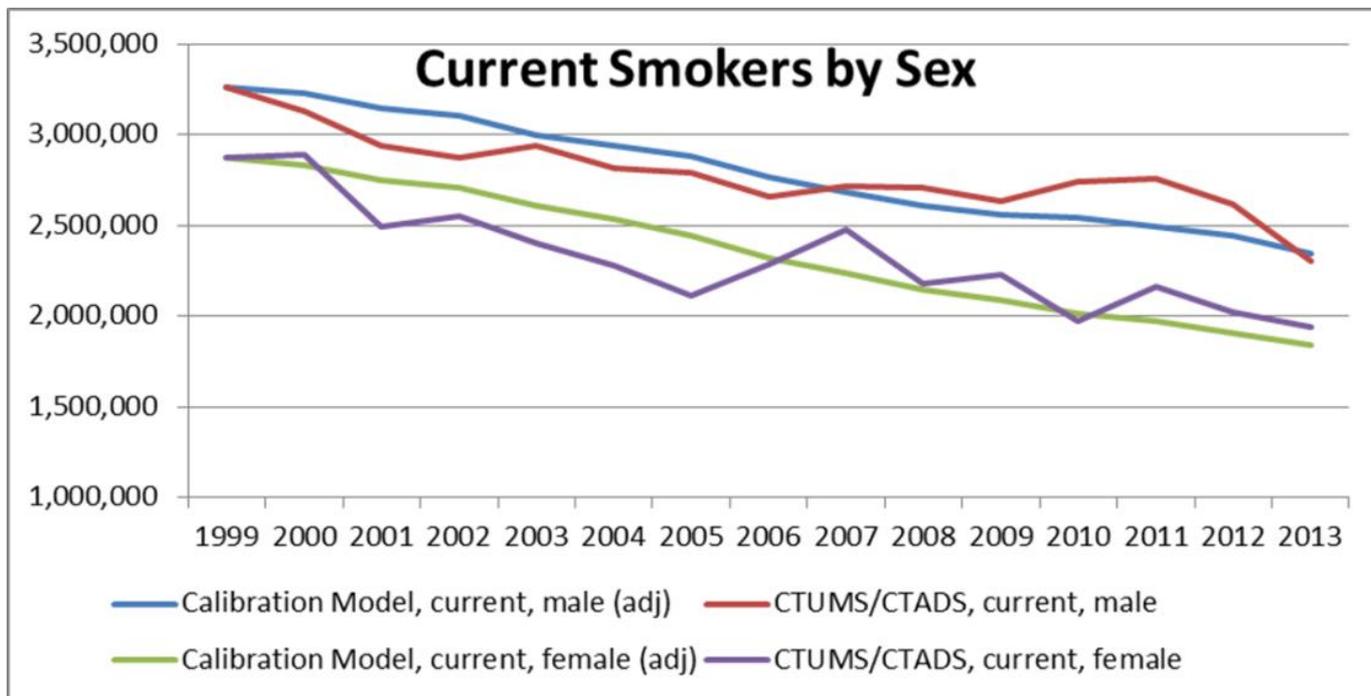
Modelling of Potential Health Benefits

- Health Canada commissioned a modelling study to evaluate the potential public health benefits of implementing a nicotine standard in Canada. (completed July 2017 by Industrial Economics, Inc.)
- A simulation model was created using current population survey data and expert opinion on the behavioural implications of the standard.
- Purpose of the study is to explore the potential impacts of such a measure in a Canadian context.
- Study was not undertaken to support implementation of an actual regulatory requirement.

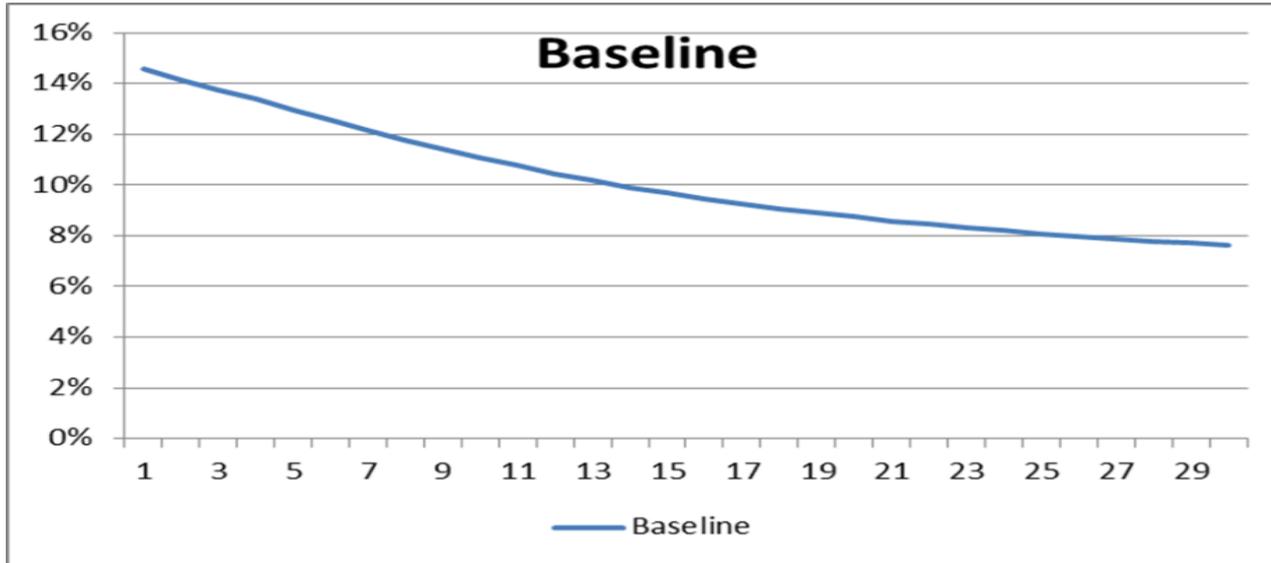
Modelling of Baseline Scenario

- Model creates **baseline scenario** (i.e. no intervention) that is used to compare against the health impacts of alternative scenarios.
- The baseline projection estimates the percentage of the Canadian population that will use cigarettes and/or e-cigarettes over next 30 years and then estimates of the total health impacts related to their use.
- Key model variables, including initiation rates, product switching rates and cessation rates, were derived using data from surveys¹ or using data obtained from the peer-reviewed literature.
- Model assumes contraband tobacco in the Canadian market would be set at 15% and that the relative harm of e-cigarettes is 20% of the harm caused by cigarettes.

Current Smokers by Sex (Age 15+): CTUMS/CTADS vs. Adjusted Model Projections



SMOKING PREVALENCE, AGE 15+: BASELINE SCENARIO



- After 30 years, the model estimates that smoking prevalence in the baseline scenario would decline from 14.6 percent to 7.6 percent.

Health impacts attributable to use of cigarettes and e-cigarettes after 30 years (baseline scenario)

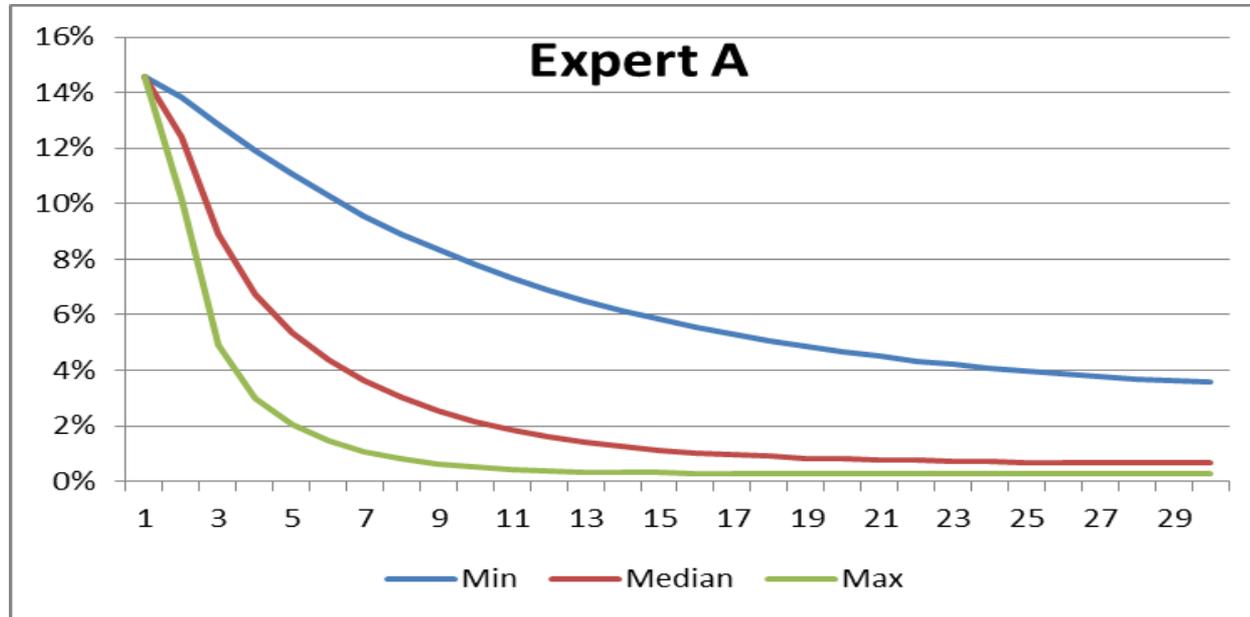
- Model estimates that a total of about 1.7 million excess deaths would result from the use of cigarettes and e-cigarettes.
- Total health impacts – including both mortality and morbidity impacts – would have a present value of about \$6.7 trillion.

SCENARIO	TOTAL DEATHS	PRESENT VALUE OF HEALTH IMPACTS (BILLION 2015 \$CAD)
Baseline	1,700,000	\$6,700

Modelling of Product Standard Scenario

- For the **product standard scenario** (i.e. implementation of a standard mandating a very low amount of nicotine in cigarettes), the variables of the model were adjusted based on expert input to estimate the impact of the standard over a 30-year period.
- Experts were asked to estimate the impact of the standard on the rate of Canadians initiating cigarette use or e-cigarette use, quitting cigarettes, switching to e-cigarettes, dual use of cigarettes and e-cigarettes and quitting e-cigarette use altogether.
- The study assumed for modeling purposes:
 - That the standard would set amount of nicotine in cigarettes to levels that could neither establish nor sustain addiction.
 - That non-tobacco products would remain available as alternative sources of nicotine, such as e-cigarettes.

SMOKING PREVALENCE, AGE 15+: MINIMUM, MEDIAN, AND MAXIMUM ESTIMATES FROM EXPERTS: PRODUCT STANDARD SCENARIO



Model estimates of the benefits as a result (product standard scenario)

TOTAL REDUCTION IN DEATHS DUE TO THE POTENTIAL PRODUCT STANDARD: MINIMUM, MEDIAN, AND MAXIMUM ESTIMATES

SCENARIO	MINIMUM	MEDIAN	MAXIMUM
Expert A	150,000	390,000	460,000

TOTAL REDUCTION IN THE PRESENT VALUE OF HEALTH IMPACTS DUE TO THE POTENTIAL PRODUCT STANDARD: MINIMUM, MEDIAN, AND MAXIMUM ESTIMATES (BILLION 2015 \$CAD)

SCENARIO	MINIMUM	MEDIAN	MAXIMUM
Expert A	\$370	\$1,100	\$1,400

Results

- Model predicts that a product standard that limits the amount of nicotine in cigarettes to non-addictive levels could yield significant population health benefits by reducing smoking and second-hand smoke exposure.
- Based on the expert's median estimate of behaviour change, if a nicotine product standard were implemented, the smoking rate would fall below 8% within four years, and decline to 5% within seven years. This rapid decline is driven primarily by users switching from cigarettes to e-cigarettes.
- Over a 30-year period, the analysis estimates that the measure could prevent some 360,000 to 480,000 premature deaths and reduce the costs associated with health impacts (including those related to both death and disease) by CAN\$1.0 to 1.4 trillion¹.

¹Treasury Board Secretariat's guidelines on cost-benefit analysis, attributes a cost of CAN\$7.4 million per premature death

Limitations

- Study by IEC based on the opinions of a panel of independent experts, different models or different experts could result in different predictions.
- Changes in the model's assumptions can affect the results and future research could inform on how to address potential unintended consequences.

Next Steps

- Health Canada will continue to explore and conduct additional research to understand the potential health benefits that would result from the implementation of measures to reduce the addictiveness of tobacco products.
- Since addiction is recognized as an important driver of tobacco use, reducing the addictiveness of tobacco products is one of the options being explored under the federal approach to tobacco control in order to drive down tobacco use to less than 5% by the year 2035.

For questions of comments, please contact:

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