

# SMOKE-FREE PRODUCTS: AN OPPORTUNITY FOR PUBLIC HEALTH?

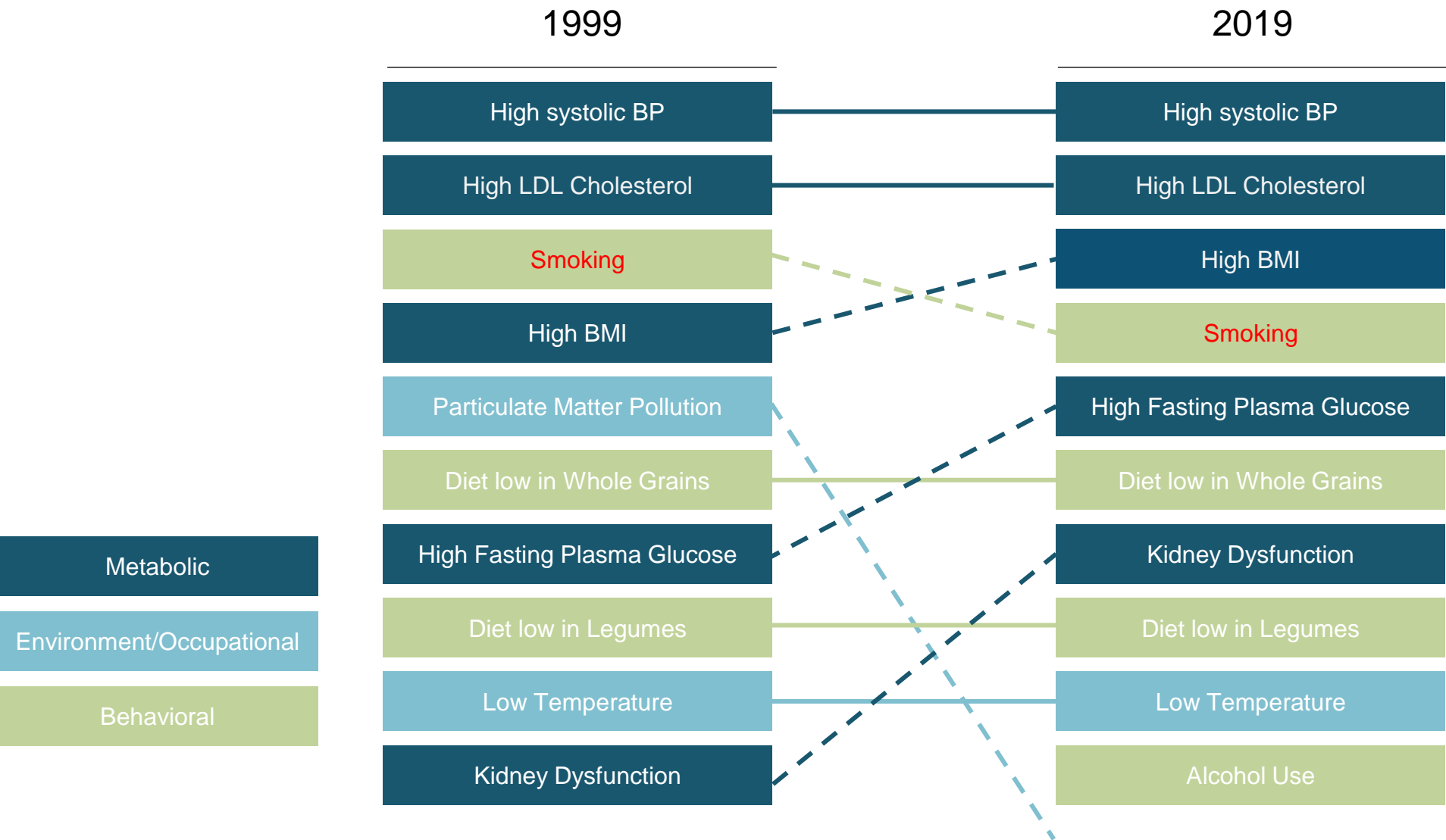
September 14<sup>th</sup>, 2022

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# Smoking remains a major risk factor for NCD-related mortality in Latvia





# Tobacco Harm Reduction

A Complement to Current Approaches

## Smoking-Related Diseases

Smoking is addictive and causes a number of serious diseases

1

## Number of Smokers

It is estimated that almost 1 billion people worldwide will continue to smoke in the foreseeable future\*

2

## Smoke-Free Alternatives

Offering smoke-free alternatives to adult smokers is a sensible, complementary addition to existing tobacco control strategies

3

Latvia (2020):  
Smoking prevalence ≈ 24%\*\*

Almost  
1,000,000,000

\*Source: WHO 2021. [Global report on trends in prevalence of tobacco use 2000-2025, fourth edition](#) (last accessed: June 7th, 2022)

\*\* 2020 Smoking prevalence (population aged 15-64) Source: Disease prevention and control center-Latvia-Health Statistics database - [Statistikas dati](#) | SPKC



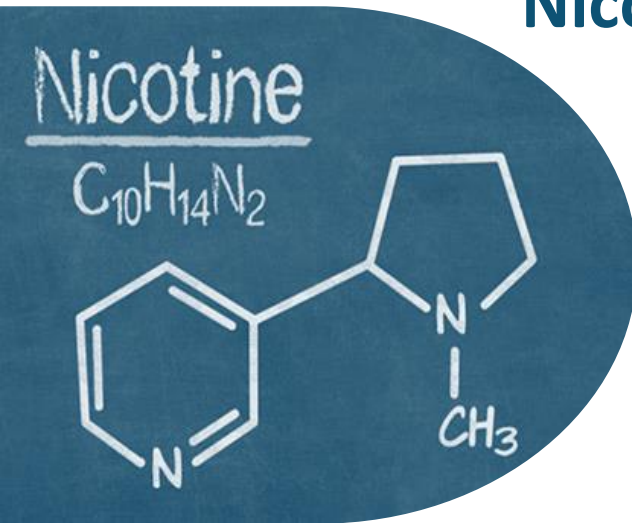
# Population Harm Reduction



**Successful Harm Reduction Requires That Current Adult Smokers Be Offered a Range of Reduced-Risk Products So That Consumer Acceptance Can Be Best Fulfilled**



# Nicotine Is Not the Primary Cause of Disease



“

**Nicotine ... is not what makes tobacco use so deadly.**

Tobacco and tobacco smoke contain thousands of chemicals. It is this **mix of chemicals—not nicotine—that causes serious disease and death** in tobacco users, including fatal lung diseases, like chronic obstructive pulmonary disease (COPD) and cancer.

[US FDA Website](#) (Accessed: 10 April 2021)

”

**Nicotine, though addictive and not risk-free, is not the primary cause of smoking-related disease**

“

4 out of 10 smokers and ex-smokers wrongly think nicotine causes most of the smoking-related cancers, when **evidence shows nicotine actually carries minimal risk of harm to health.**

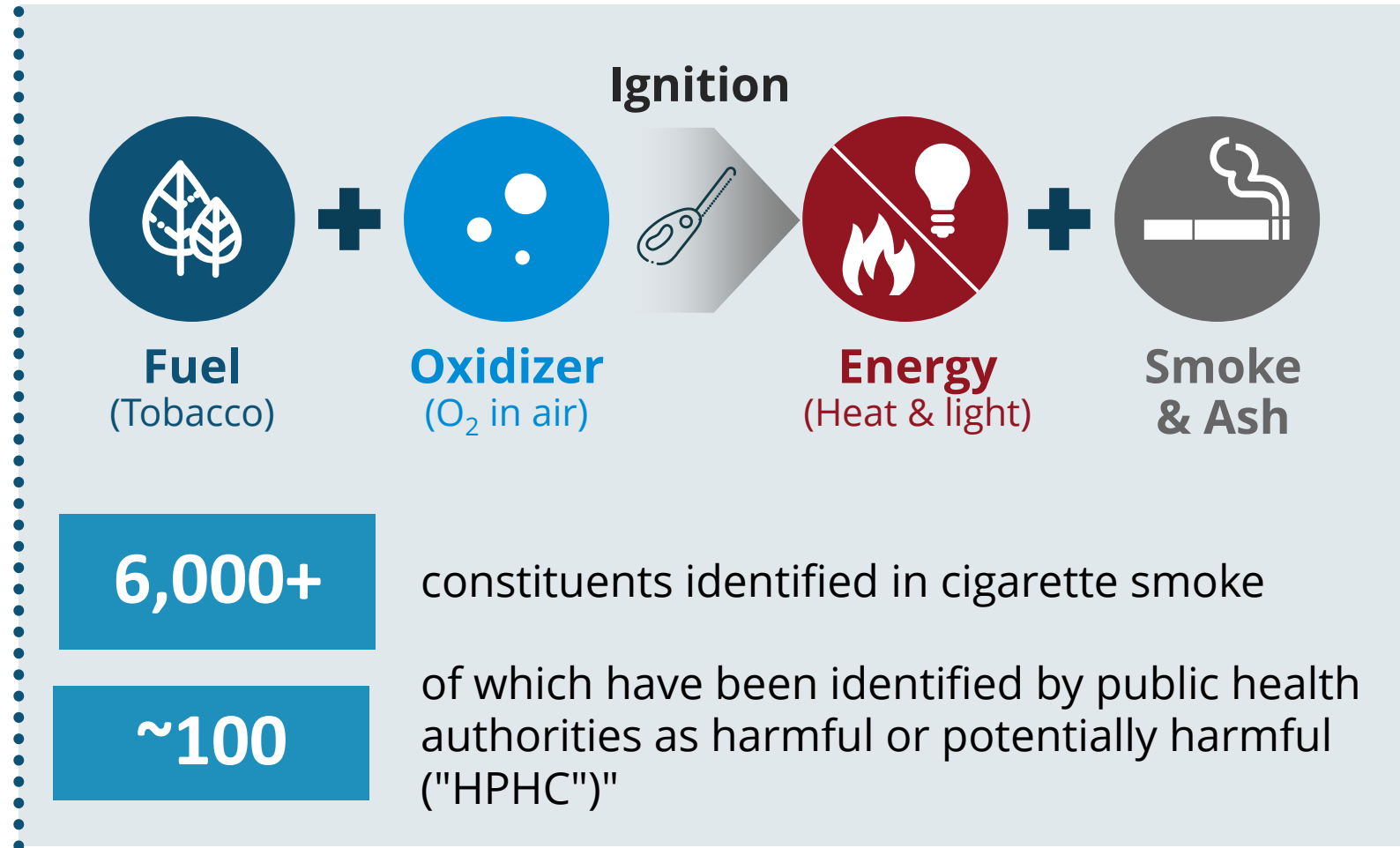
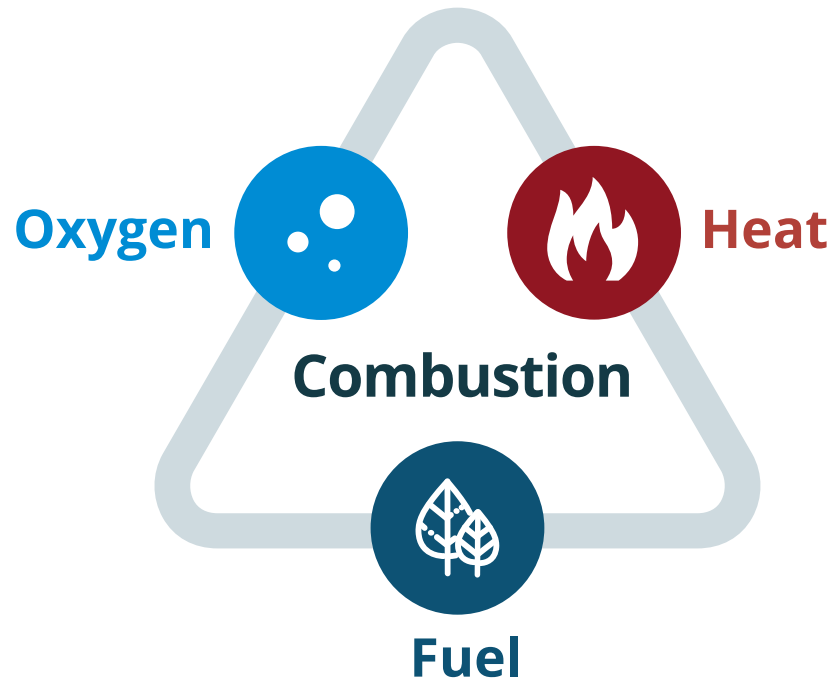
[Public Health England Website](#) (Accessed: 10 April 2021)

”



# Understanding Combustion

## Tobacco Combustion





# PMI's Portfolio of Smoke-Free Alternatives

## Heated Tobacco Products

### Electrically Heated Tobacco Products

Tobacco Heating System (THS)



Pin-Based Heating System (PHS)



### Aerosol Heated Tobacco Products

Aerosol Heating Tobacco System (AHTS)



## Nicotine-Containing Products

### Nicotine Salt Products

Nicotine Salt Powder System (NPS)



### E-Vapor Products

MESH Vaping System (MVS)



### Oral Nicotine Products

Nicotine Pouches





# Population Harm Reduction

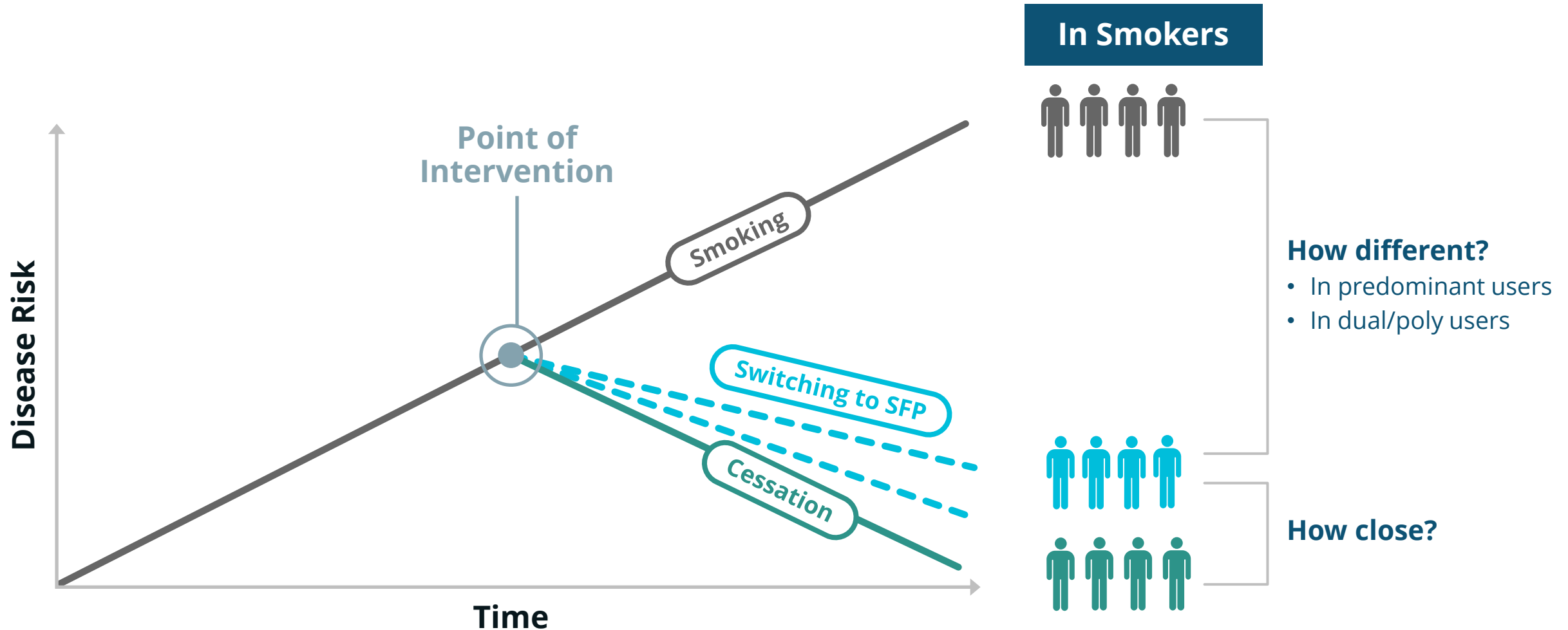


**Successful Harm Reduction Requires That Current Adult Smokers Be Offered a Range of Reduced-Risk Products So That Consumer Acceptance Can Be Best Fulfilled**





# Smoking Cessation Is the “Gold Standard” for Risk Reduction

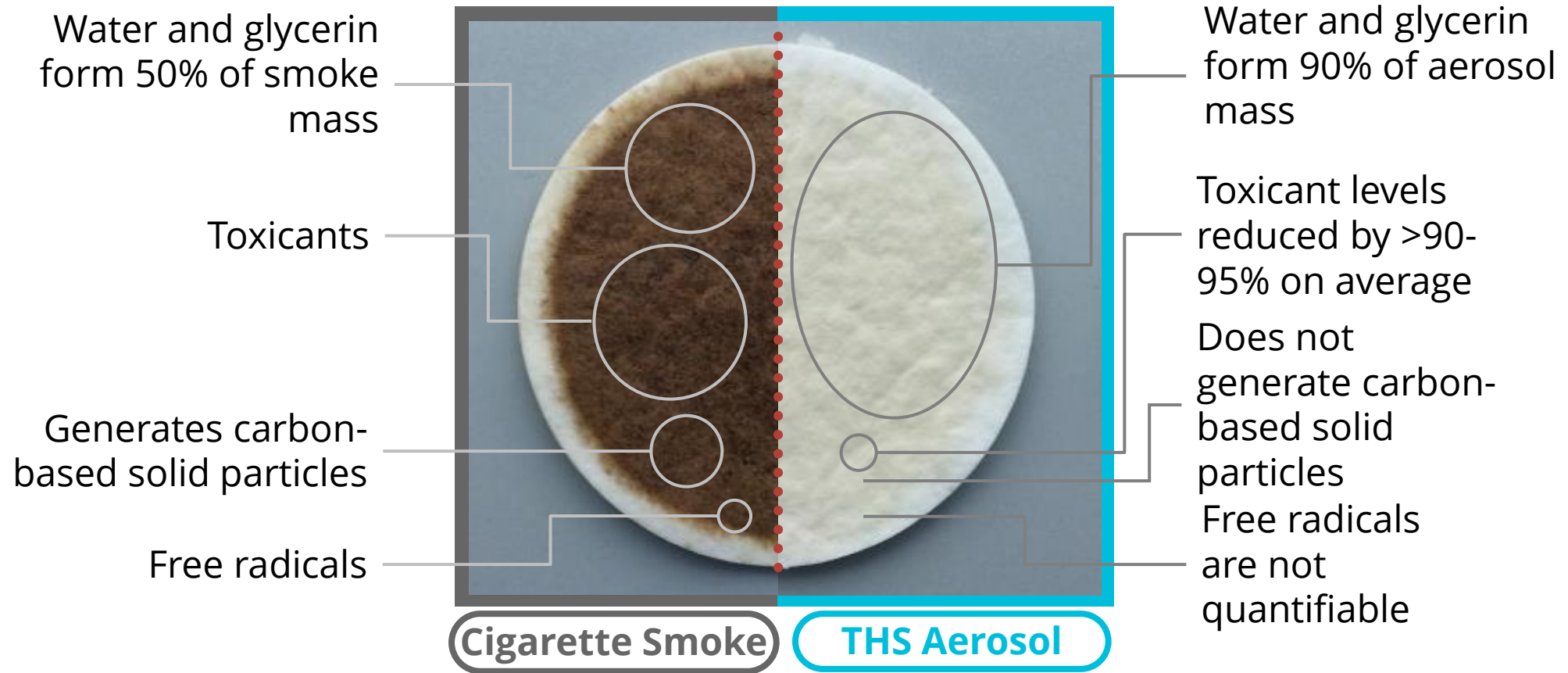


Source: Adapted from Institute of Medicine (2012), Scientific Standards for Studies on Modified Risk Tobacco Products. SFP: Smoke-free product) "Conceptual depiction for illustration purposes only. The accumulation of disease risk and the reduction upon cessation and switching to a smoke-free product follow different trajectories for specific diseases."



# The Difference between THS Aerosol & Cigarette Smoke

## Aerosol Chemistry & Physics



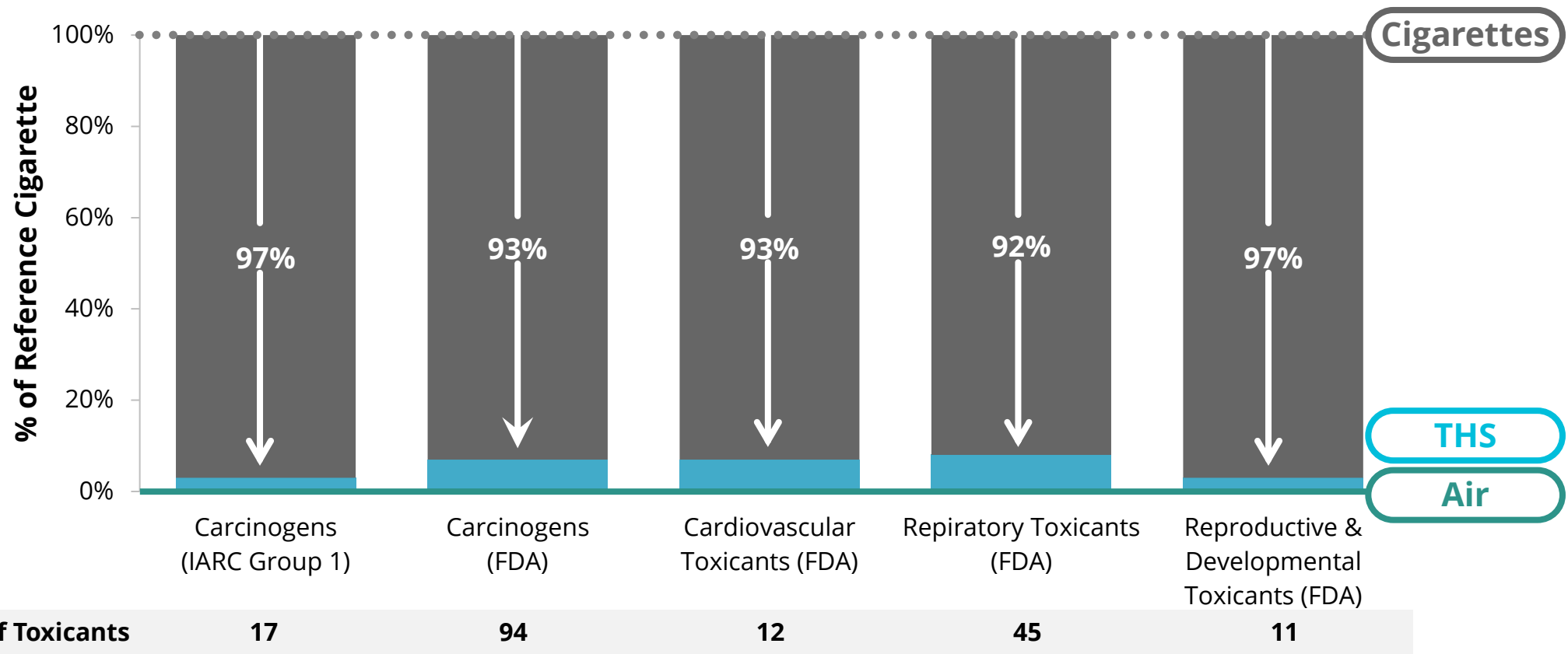
**Smoke and Aerosol Were Collected on a Cambridge Filter Pad in Accordance with the Health Canada Intense Smoking Regimen**



# Reduced Formation of Toxicants

Aerosol Chemistry & Physics

Average Reduction in *Formation* of Harmful or Potentially Harmful Constituents with THS Relative to the Levels Measured in Smoke from the 3R4F Reference Cigarette, by Disease Category\*



THS = Tobacco Heating System; Health Canada's Intense Smoking Regime; Comparison on a per-stick basis (excluding nicotine)  
\*Analysis of the FDA-93 Harmful or Potentially Harmful Constituents included more than 93 individual compounds because the FDA-93 includes some classes or isomers

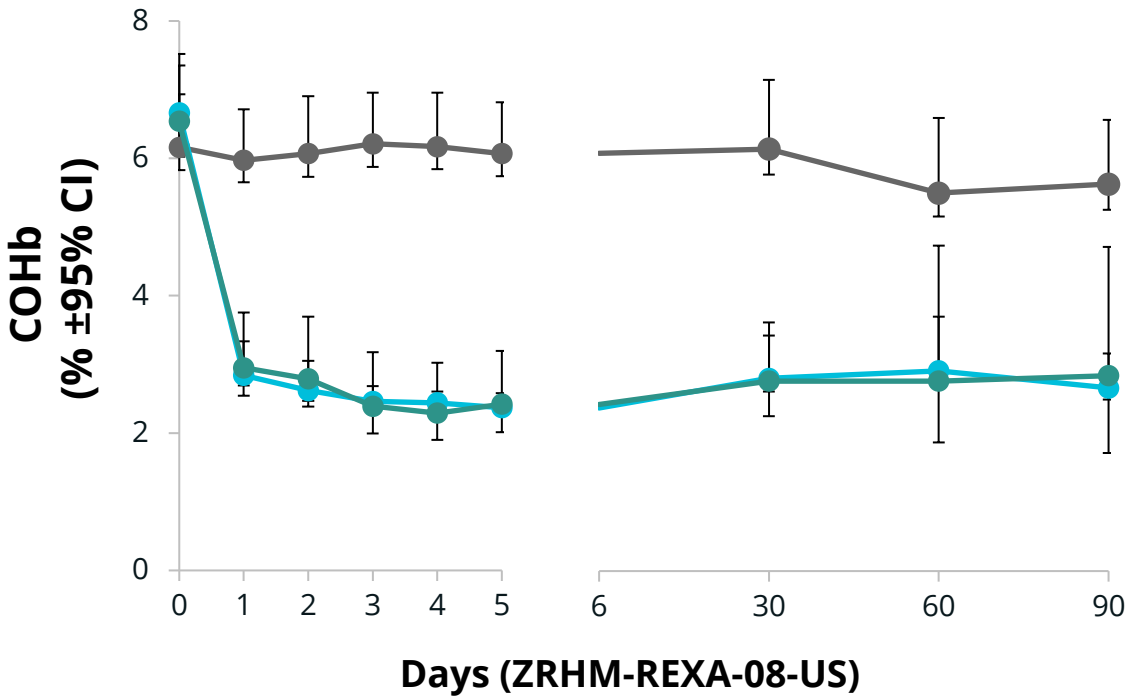
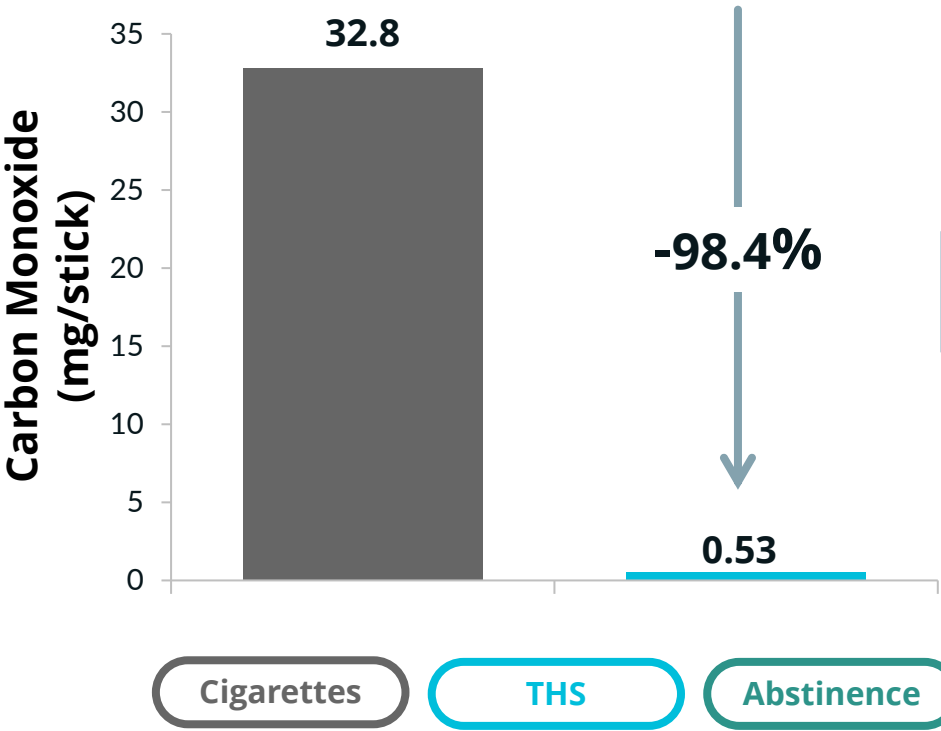


# Reduced Exposure – Carbon Monoxide (COHb)

Clinical Assessment *(in Smokers Who Would Otherwise Continue to Smoke Cigarettes)*

HPHCs Are Drastically Reduced In THS Aerosol

Exposure Is Significantly Reduced After Switching to THS 





# Reduced Exposure

Clinical Assessment *(in Smokers Who Would Otherwise Continue to Smoke Cigarettes)*

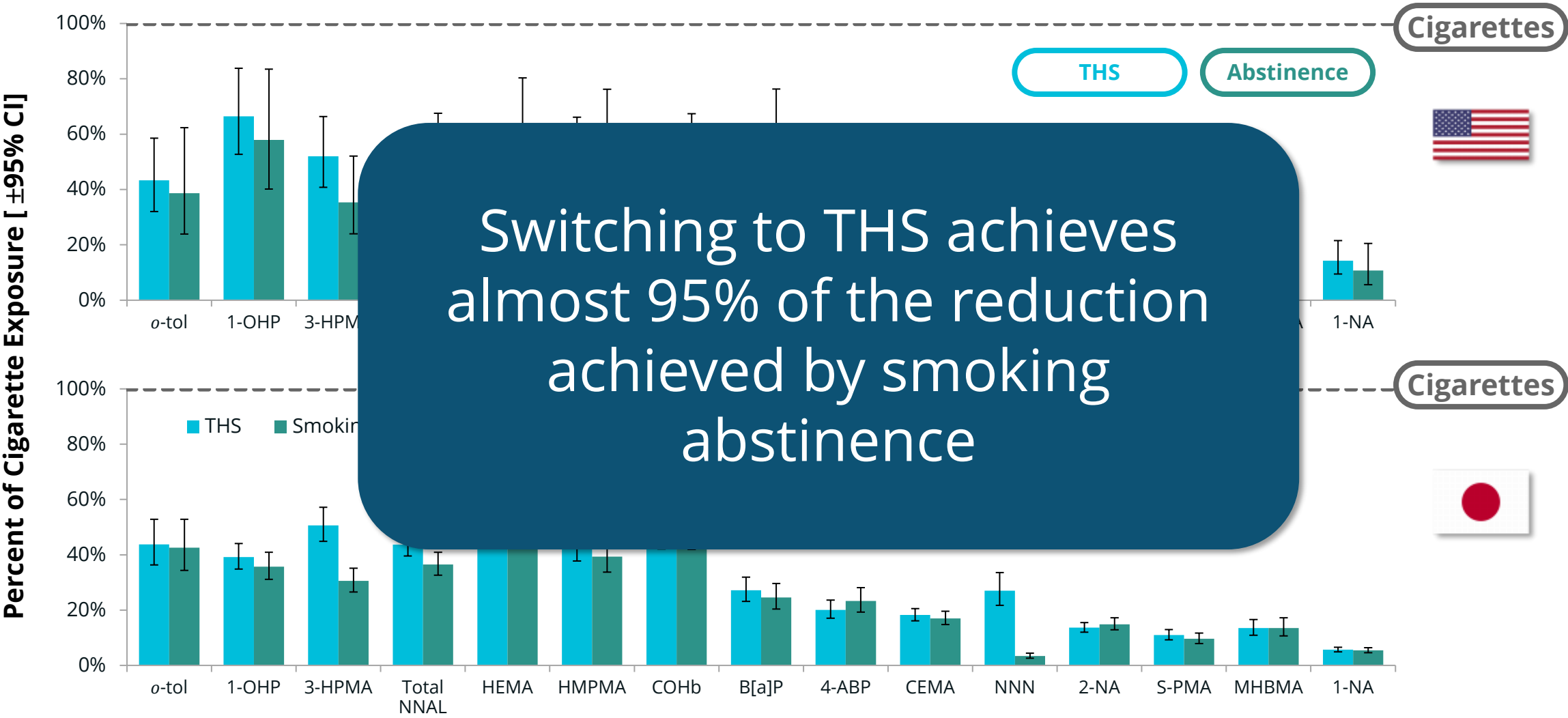


Sources: Bottom: REXA-07-JP (NCT01970995) — Lüdicke, 2018 (DOI: 10.1093/ntr/ntx028); Top: REXA-08-US (NCT01970995) — Haziza, 2019 (DOI: 10.1093/ntr/ntz013)



# Reduced Exposure

Clinical Assessment *(in Smokers Who Would Otherwise Continue to Smoke Cigarettes)*



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# Population Harm Reduction

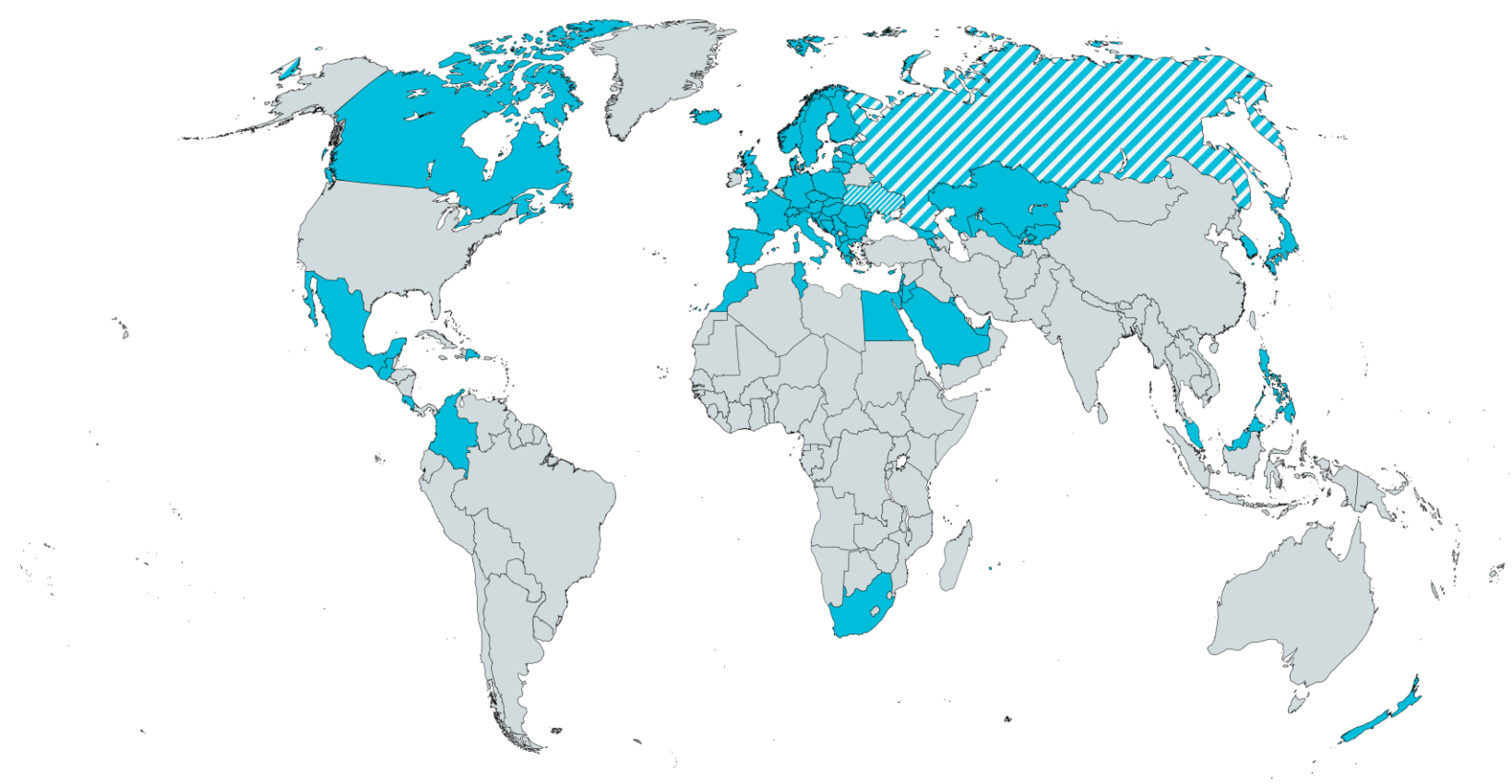


**Successful Harm Reduction Requires That Current Adult Smokers Be Offered a Range of Reduced-Risk Products So That Consumer Acceptance Can Be Best Fulfilled**



# Progress toward Commercialization of Smoke-Free Products

Launched in Key Cities or Nationwide in 71 Markets\*

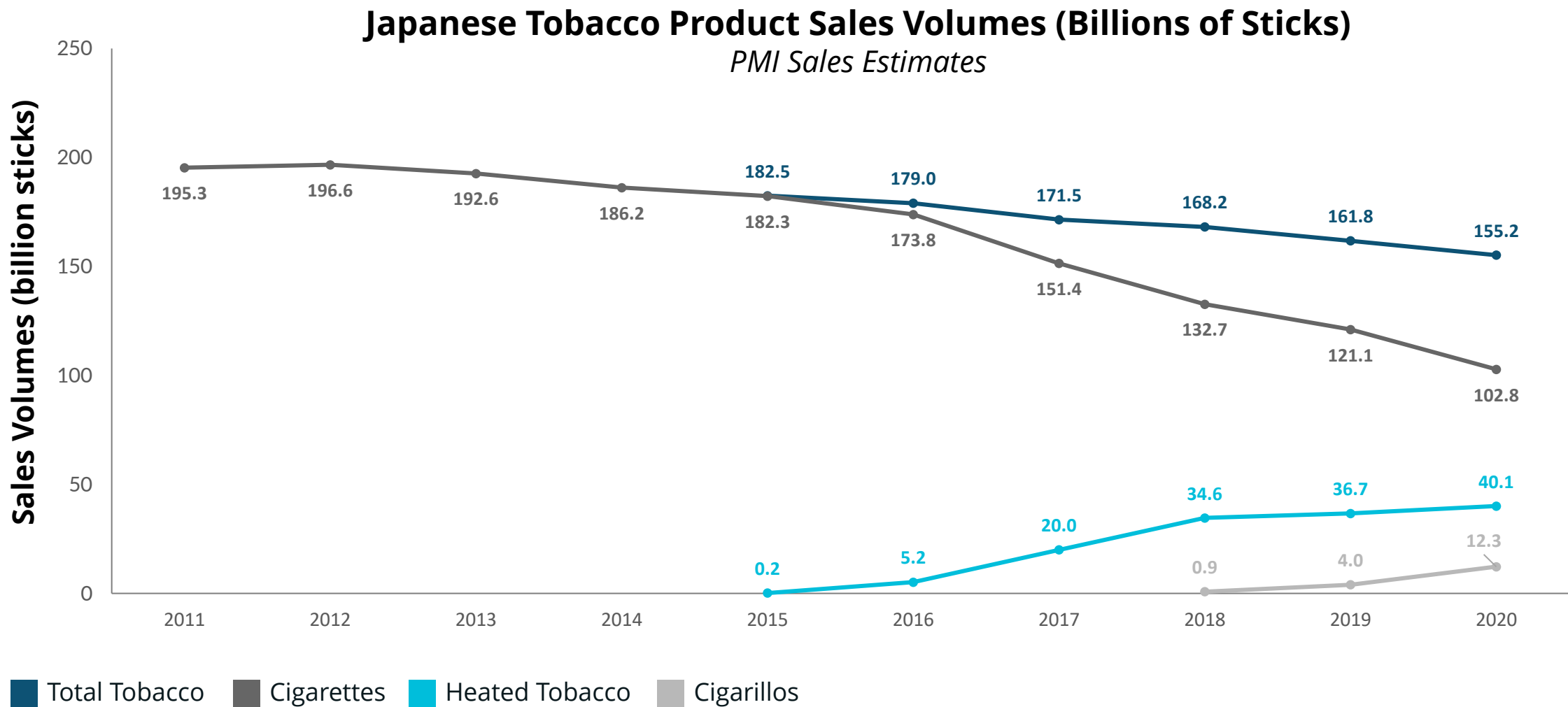


**The Number of Users of THS Stands at 19 Million, of Whom 13.2 Million (70%) Have Stopped Smoking\***

\*Status as of June 30th, 2022. Numbers exclude Russia and Ukraine, which had an additional 4.8 million users as of December 31st, 2021. the number of users are PMI estimates source: PMI Q2 2022 Earnings Report



# In-Market Sales Volumes



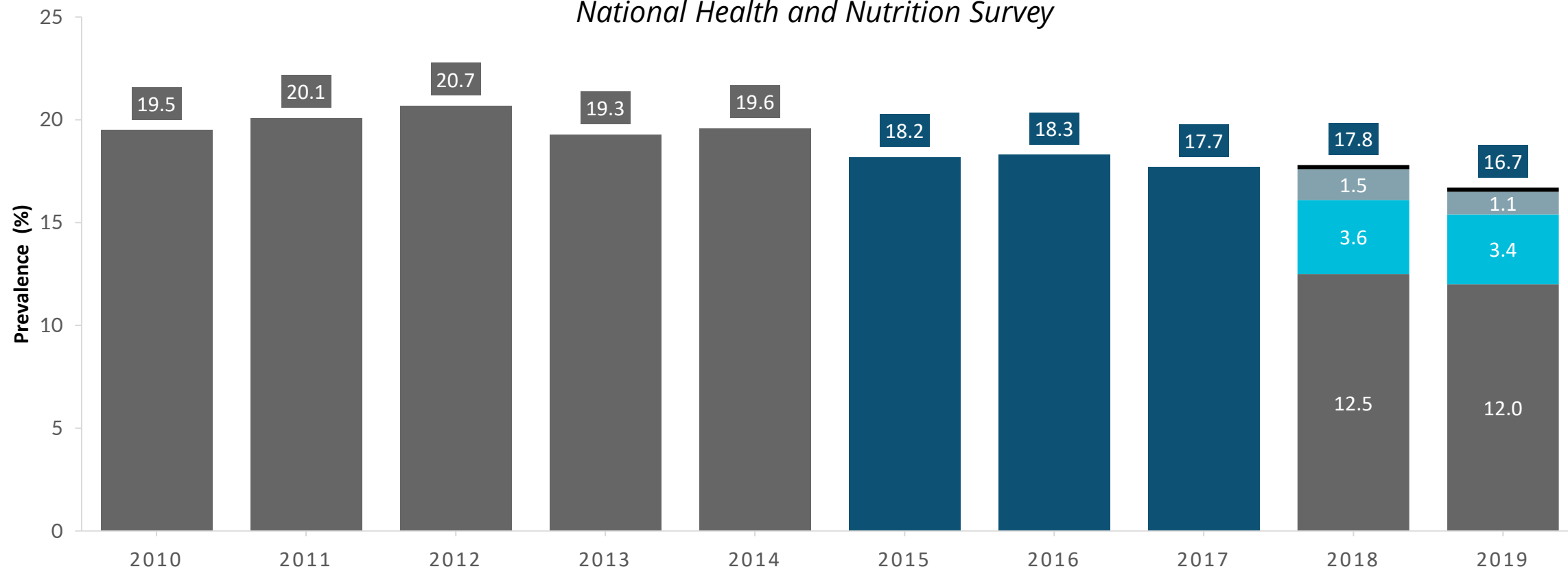
# Prevalence of Tobacco Use in Japan

National Health and Nutrition Survey



## Japanese Adult ( $\geq 20$ years) Tobacco Use Prevalence

*National Health and Nutrition Survey*



■ Total Tobacco ■ Cigarettes (only) ■ Heated Tobacco (only) ■ Dual Use (Cigarettes + Heated Tobacco) ■ Other

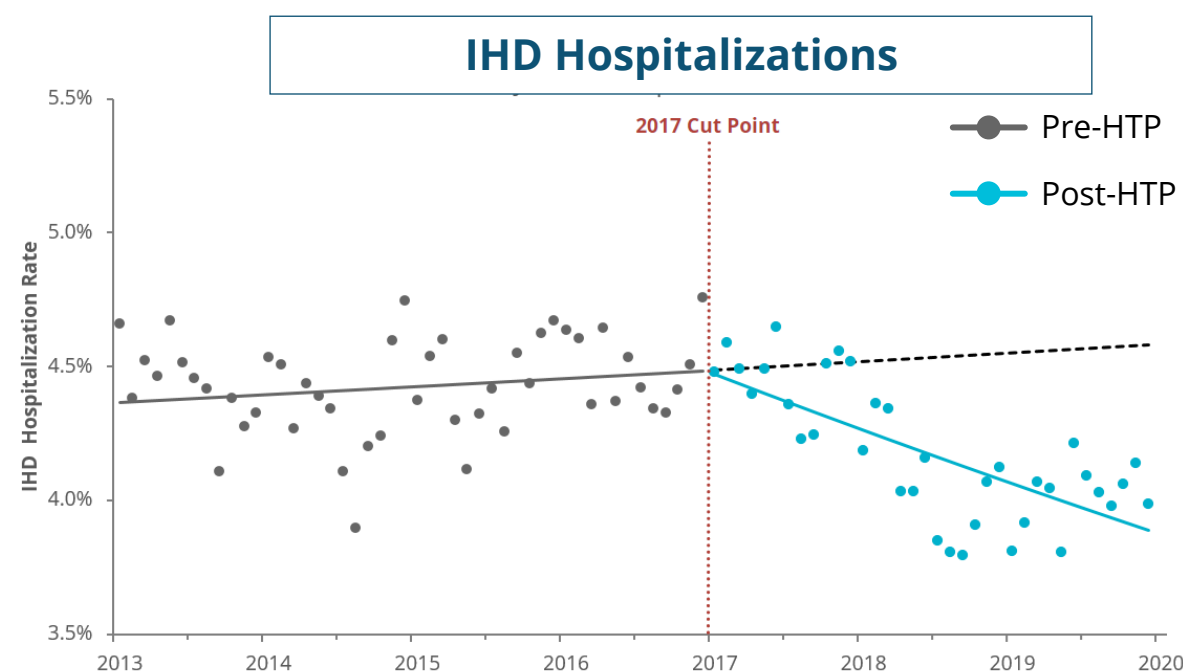
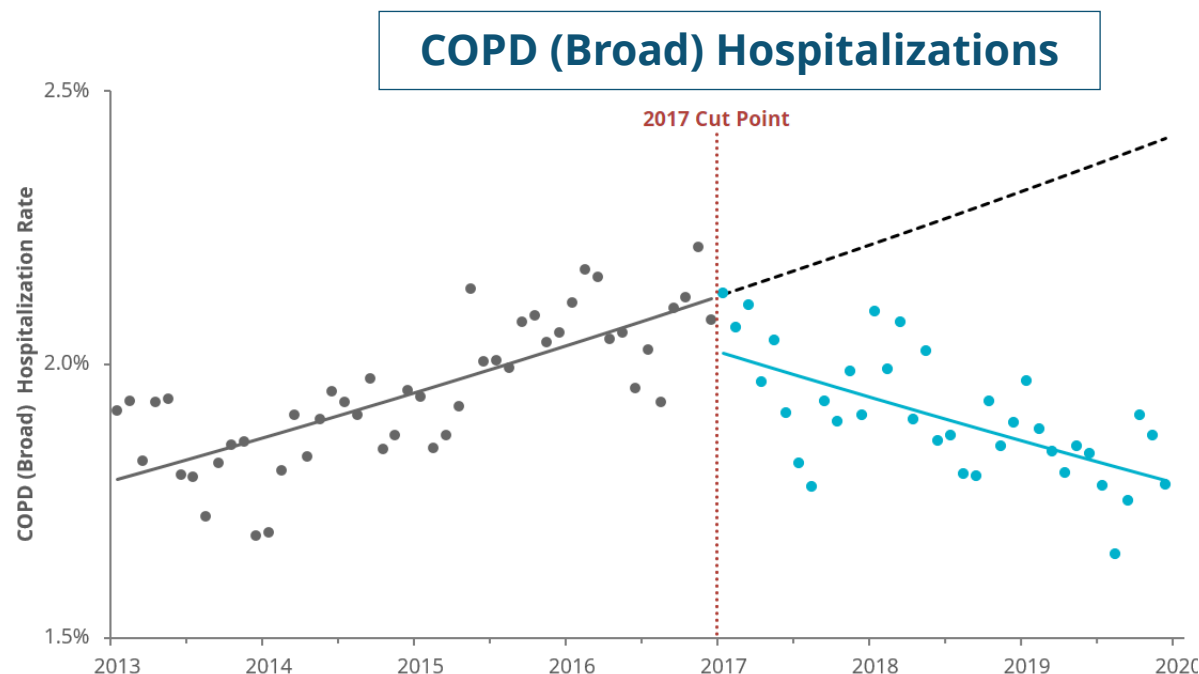
# Real-World Ecological Study

## Interrupted Time Series Analysis



### Hospitalization Rate Over Time

Japan Medical Data Center (JMDC) Study – All Hospital Records



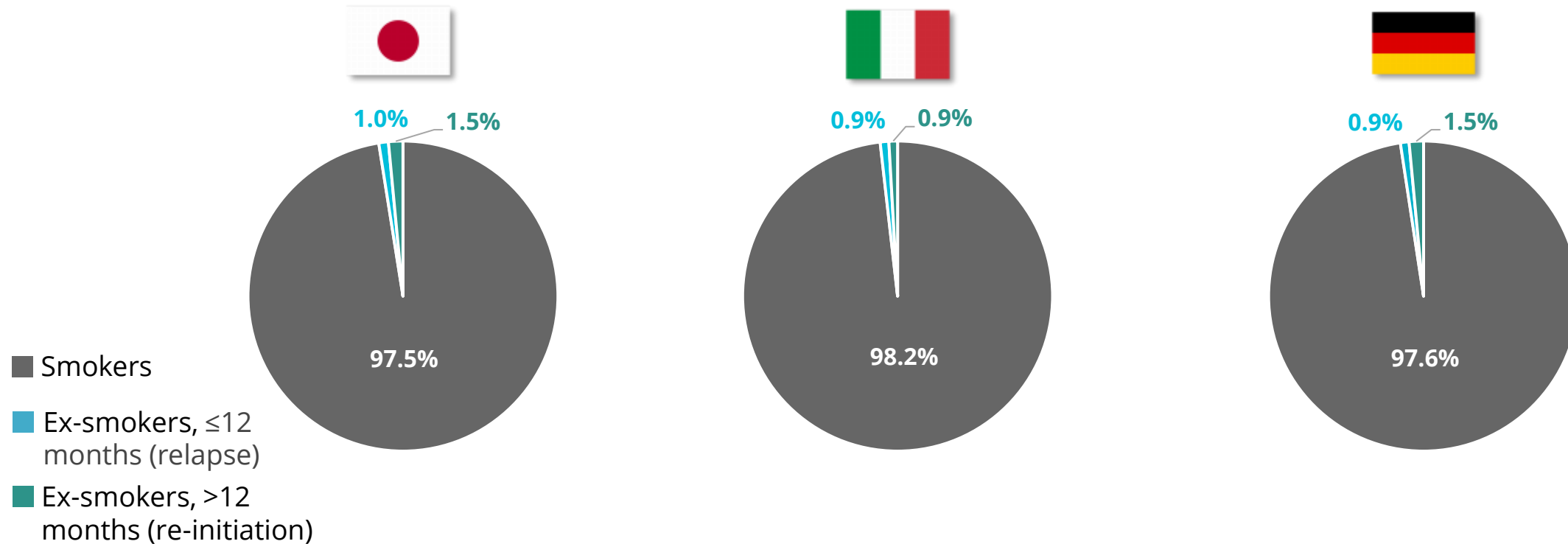
COPD = Chronic Obstructive Pulmonary Disease; IHD = Ischemic Heart Disease. HTP = Heated Tobacco Products. Model: adjusting for age and sex – other confounding factors that could influence hospitalization rates have not been fully analyzed. This is an ecological study looking at temporal associations and not designed to assess causality and is subject to the inherent limitations of ecological analyses.



# Study Results | Tobacco Relapse/Re-initiation (2019)

IQOS™ USER SURVEY

## Smoking Status at Time of THS Initiation (%)



**More than 97% of Current THS Users Were Already Smoking Cigarettes When They Started to Use THS**

# Youth and never-smoker initiation of THS



Prof. Yoneatsu Osaki “Nationwide survey on smoking and drinking behaviors” shows low youth initiation with heated tobacco products, no “gateway to smoking” for younger generation.



BZgA “Alcohol survey 2019 and trends” shows heated tobacco products are not initiation products for minors.



Addiction Suisse “Health Behavior in School-aged Children” shows low youth use of heated tobacco products.



The U.S. FDA, in its decision on *IQOS* commercialization in the U.S., concluded based on PMI’s data from Japan, Italy, and the U.S. that “Available data, while limited, also indicate that few non-tobacco users would be likely to choose to start using *IQOS*, including youth.”

# Smoke-free products: an opportunity for public health?



## Conclusions:

- ✓ Totality of evidence indicate to the direction that: Switching to THS completely, while not risk-free, is a better choice for adults who would otherwise continue smoking.
- ✓ Majority of THS users no longer smoke cigarettes
  - Non-smokers and ex-smokers rarely initiate or re-start tobacco or nicotine use with THS
  - Almost every THS user has a history of tobacco or nicotine use
  - Published literature indicates a low prevalence of THS use in youth
- ✓ Decline of smoking prevalence has accelerated in Japan since introduction of HTPs
- ✓ U.S FDA authorized the commercialization of THS as a MRTP with reduced-exposure claims (commercializing the product with such information is expected to “promote public health.”)
- ✓ Continuous monitoring of product use will help avoiding unintended consequences

# OTHERS HAVE A ROLE: GOVERNMENTS



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# Science in support of policy for Smoke-Free Products



## Balancing Consideration of the Risks and Benefits of E-Cigarettes

David J. K. Balfour, DSc, Neal L. Benowitz, MD, Suzanne M. Colby, PhD, Dorothy K. Hatsukami, PhD, Harry A. Lando, PhD, Scott J. Leischow, PhD, Caryn Lerman, PhD, Robin J. Mermelstein, PhD, Raymond Niaura, PhD, Kenneth A. Perkins, PhD, Ovide F. Pomerleau, PhD, Nancy A. Rigotti, MD, Gary E. Swan, PhD, Kenneth E. Warner, PhD, and Robert West, PhD

The topic of e-cigarettes is controversial. Opponents focus on e-cigarettes' risks for young people, while supporters emphasize the potential for e-cigarettes to assist smokers in quitting smoking. Most US health organizations, media coverage, and policymakers have focused primarily on risks to youths. Because of their messaging, much of the public—including most smokers—now consider e-cigarette use as dangerous as or more dangerous than smoking. By contrast, the National Academies of Science, Engineering, and Medicine concluded that e-cigarette use is likely far less hazardous than smoking. Policies intended to reduce adolescent vaping may also reduce adult smokers' use of e-cigarettes in quit attempts.

Because evidence indicates that e-cigarette use can increase the odds of quitting smoking, many scientists, including this essay's authors, encourage the health community, media, and policymakers to more carefully weigh vaping's potential to reduce adult smoking-attributable mortality.

We review the health risks of e-cigarette use, the likelihood that vaping increases smoking cessation, concerns about youth vaping, and the need to balance valid concerns about risks to youths with the potential benefits of increasing adult smoking cessation. (*Am J Public Health*. Published online ahead of print August 19, 2021;1–12. <https://doi.org/10.2105/AJPH.2021.306416>)

The use of nicotine-containing electronic- or e-cigarettes has divided the tobacco control community along a spectrum from fervent opponents to enthusiastic supporters. Opponents emphasize that vaping can cause nicotine addiction among young people and could lead some to become dependent cigarette smokers, possibly “renormalizing” smoking. They cite research indicating that nicotine may harm adolescents' developing brains. Some consider vaping's health risks substantial, and some question whether vaping decreases smoking cessation.<sup>1</sup> By contrast, proponents present evidence that vaping assists smokers in quitting smoking and believe that vaping poses far less risk to users' health than does smoking. Smoking among youths,

they observe, has declined rapidly during vaping's ascendancy.<sup>2</sup>

Many US governmental health agencies<sup>3–6</sup> and nongovernmental medical<sup>7,8</sup> and health organizations<sup>9–12</sup> focus primarily on vaping's risks for young people. These organizations' pronouncements and their influence on policymakers and the media have had a profound impact on the public's understanding of vaping. A study of US news articles on e-cigarettes found that, from 2015 to 2018, 70% of articles mentioned vaping's risks for youths, while only 37.3% noted potential benefits for adult smokers.<sup>13</sup> Of respondents to a 2019 national survey, nearly half considered vaping nicotine just as harmful as or more harmful than cigarette smoking. Only 1 in 8 considered vaping less harmful. (The rest

responded “I don't know.”<sup>14</sup>) By contrast, the US National Academies of Sciences, Engineering, and Medicine<sup>15</sup> and the British Royal College of Physicians<sup>16</sup> have concluded that vaping is likely far less hazardous than smoking cigarettes.

The public's inaccurate perception worsened following a 2019 vaping-associated acute pulmonary disease outbreak (named “e-cigarette or vaping use-associated lung injury” [EVALI]) that caused 68 fatalities.<sup>17</sup> Media coverage was extensive. Several states and cities promptly banned retail and online sale of flavored e-cigarettes.<sup>18</sup> In early 2020, however, research attributed the illness to vitamin E acetate, an adulterant in illicit tetrahydrocannabinol (THC) vaping devices shown to produce pulmonary injury in animals.<sup>19–21</sup> A small percentage

- Not risk-free but likely far less harmful than smoking
- Cigarette smoking declined at unprecedented rate
- Dual use does not have comparable benefit but may be necessary for some smokers to transition from smoking
- Frequent vaping most common in current or former smokers

*“We believe the potential lifesaving benefits of e-cigarettes for adult smokers deserve attention equal to the risks to youths.”*

*“While evidence suggests that vaping is currently increasing smoking cessation, the impact could be much larger if the public health community paid serious attention to vaping's potential to help adult smokers, smokers received accurate information about the relative risks of vaping and smoking, and policies were designed with the potential effects on smokers in mind.”*

Analytic Essays Peer Reviewed Balfour et al. e1

<https://ajph.aphapublications.org/doi/10.2105/AJPH.2021.306416>



# More governments are recognizing the potential of Smoke-Free products



## USA

- Nicotine strategy recognizes benefits of non-combusted products
- Process for authorizing scientifically-substantiated claims



## Greece

- Tobacco harm reduction integrated into tobacco control strategy
- Law amended to allow science-based claims for novel products



## Philippines

- Separate regulatory framework established for Vaporized Nicotine and Non-Nicotine Products
- Differentiated



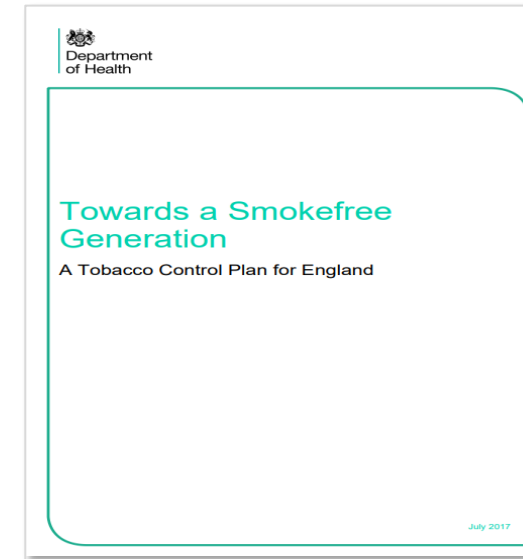
## Switzerland

- 2021 law established dedicated categories and health warnings for HTPs, e-cigs and nicotine pouches
- Science-based claims allowed for novel products

# The U.K. | “The Smokefree 2030 goal”



- 2014 UK Government’s initial proposal to regulate e-cigarettes as medicines is overridden by EU TPD
- 2015 Public Health England advises that vaping is 95% less harmful
- 2017 English Tobacco Control Plan “Towards a Smokefree Generation”
- 2019 MoH will announce new policies with new legislation to follow (2022 – 2023)
  - Independent review of tobacco control measures
  - Office for Health Disparities (new PHE) will publish its latest evidence review including HnB
  - New Tobacco Control Plan expected in 2023



#### 4. Backing evidence based innovations to support quitting

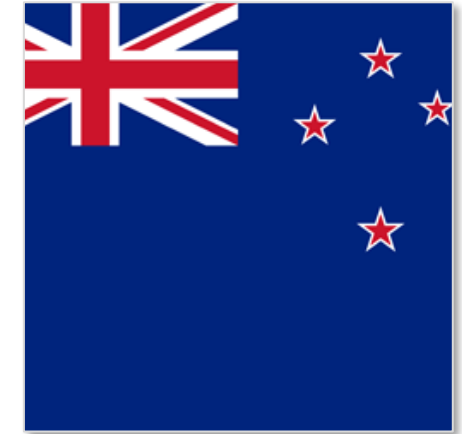
We are committed to evidence-based policy making, so we aim to:

- Help people to quit smoking by permitting innovative technologies that minimise the risk of harm.
- Maximise the availability of safer alternatives to smoking.

# New Zealand | “The Smokefree 2025 goal”



- 2011 NZ Government adopts plan to reduce smoking prevalence to below 5% by 2025
- 2017 MoH statement that vaping products are less harmful and can contribute to reaching 2025 goal
- 2020 Law establishes a “risk-proportionate” framework
  - “Strike a balance between making sure vaping products are available for smokers who want to use them as a harm reduction tool and ensuring these nicotine products aren’t marketed or sold to children.”
  - Implementing regulations for packaging reinforce differentiation
- 2021 MoH releases **Smokefree Action Plan**, focused on making **smoked tobacco products** less accessible and less appealing
  - Implement retail reduction 2024 (licensing scheme)
  - Implement low nicotine 2025
  - Implement smokefree generation 2027



THANK YOU FOR YOUR ATTENTION.

**Questions?**

**Answers.**



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