Lives Saved Report:
Saving 2.04 million lives in Japan

The impact of complementing tobacco control with harm reduction and improved lung cancer treatment by 2060

REPORT SUPPORTED BY INTERNATIONAL AND LOCAL TOBACCO HARM REDUCTION EXPERTS

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Contents

1. Executive Summary

GLOBAL PROGRESS TO END SMOKING HAS STALLED. CURRENT APPROACHES TO TOBACCO CONTROL HAVE NOT BEEN SUFFICIENT. THE WORLD HEALTH ORGANIZATION (WHO) PROJECTS THAT 1.27 BILLION PEOPLE GLOBALLY WILL SMOKE BY 2025. OVER EIGHT MILLION ANNUALLY WILL DIE FROM TOBACCO USE. THIS IS UNACCEPTABLE FROM A PUBLIC HEALTH PERSPECTIVE.

This report focuses on Japan. A total of 127.7 million people live in this country. Of these, 157,180 die prematurely every year because they use tobacco products.

In 2000, WHO reported a smoking prevalence in Japan of 31,7% and projected a decrease **from 31.7% to 15.5% by 2025.**

As of 2024, the smoking prevalence in Japan is approximately 19.4% of the adult population. This includes about 24.8% of men and 6.2% of women. The number of current smokers in Japan is around 21.2 million. It is unlikely that WHO projections will therefore be realised.

There has also been a seismic shift, as cigarette sales in Japan have declined rapidly and significantly. Between 2011 and 2023, per capita, and total cigarette sales have declined by 52.6% and 52.7% respectively. The increased sales of heated tobacco products (HTP) appear to be a factor in this dramatic decline. Electronic nicotine delivery systems (ENDS) or otherwise known as e-cigarettes, are not yet approved.

Data presented in this report shows that tobacco use contributes to several major causes of death in Japan that are set to increase over the next few decades. These include ischemic heart disease (IHD), lung cancer, COPD, and stroke. They will impose significant human and economic costs.

The report considers how tobacco harm reduction (THR) products could reduce this burden. THR products use nicotine without the deadly exposures that cause harm. THR products (e-cigarettes/vapes, heated tobacco products, snus, oral nicotine pouches, and e-shisha products) are rapidly gaining traction among consumers worldwide. But these innovations have not yet been embraced by physicians and governments as key to cutting premature deaths. Evidence suggest that the more harm reduction choices smokers are offered, the faster they reduce their smoking rates.

The report comes as the quality of evidence on the benefits of smoking cessation and THR has strengthened. Cessation at every age is associated with longer survival, and switching to vapes/e-cigarettes is almost twice as effective for cessation as nicotine replacement therapies. While long-term studies on the health benefits effects of switching to THR are still needed, results of studies using biomarkers of future diseases are promising. Biomarkers can play a crucial role in tobacco control, by providing measurable and earlier indicators of exposure to tobacco-related toxicants and the potential harm they cause.

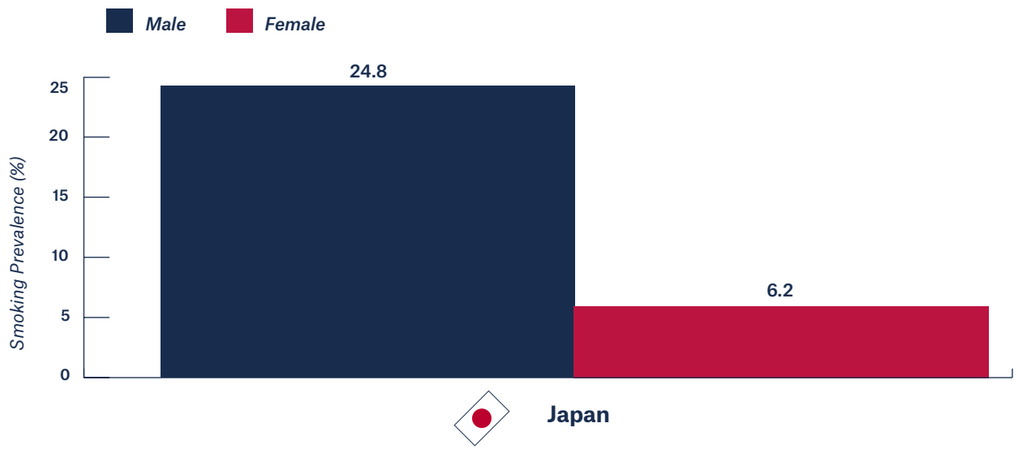
This report also comes at a time when many countries have recently reversed bans on many THR products and liberalized their approach to THR. New and innovative THR products are being developed worldwide and their role in smoking cessation and harm reduction well documented. A further sign of growing acceptance of the value of THR and the demand for them by consumers.

We note that, although the use of heated tobacco products is permitted in Japan, other THR product categories, such as ENDS, are not. If all THR products were made accessible, affordable and acceptable for those adults who cannot or will not quit, health gains would be greatly increased. The delay in preventing tobacco-related disease, disability and premature deaths calls for urgent action.

We calculated the combined impact of embracing THR, better cessation services, and improved lung cancer treatment in Japan on long term trends in health.

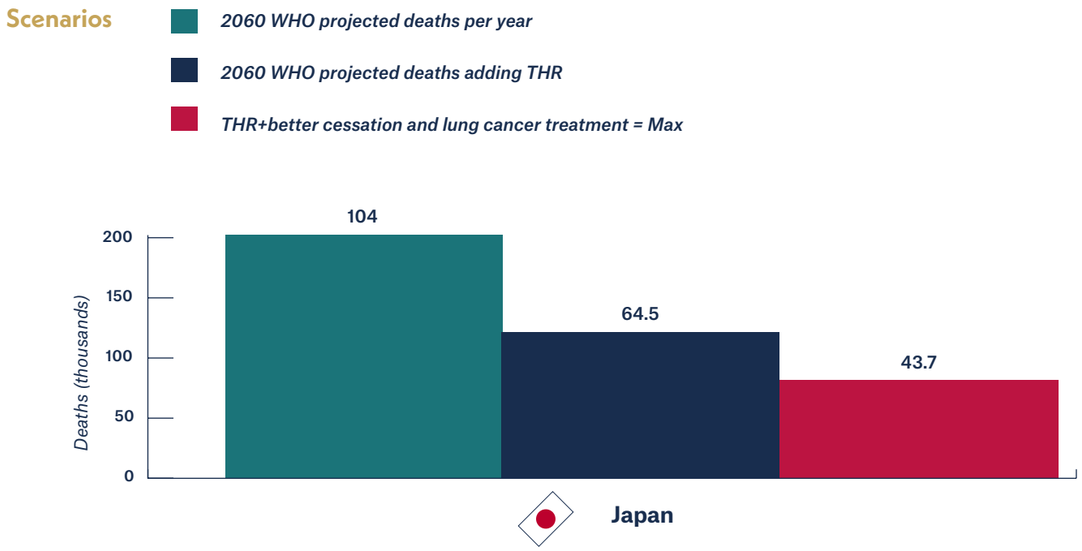
The analysis shows that over 2.04 million lives could be saved by 2060 through these interventions, compared to continuing with current WHO-directed tobacco control efforts alone.

Figure 1: Japan adult smoking rates by sex, 2023



Data source: *2022 National Health and Nutrition Survey Result (FMC and THP)*
https://www.mhlw.go.jp/stf/newpage_42694.html

Figure 2: Decrease in tobacco-related deaths, if THR were implemented in Japan along with improved cessation and early diagnosis of lung cancer



To achieve these gains, key actions are needed, including:

- **Activating health professionals (especially physicians)** to communicate the benefits of THR to patients in all clinical encounters, to counter disinformation about nicotine and the value of THR, and to develop national equivalents of the Royal College of Physicians report on THR and smokefree nicotine alternatives to provide guidance to physicians.

- **Encouraging risk-proportionate regulation:** Governments should embrace the role of harm reduction in tobacco control, as mentioned in Article 1(d) of the FCTC. They should integrate THR into broader national approaches to harm reduction by continuing to revise legislation and taxation to improve access to THR products and invest in national science and research to guide and advance THR.

- **Strengthening consumer representation:** Strengthen the role and effectiveness of independent science-based consumer groups who advocate for THR progress and do so in an integrated way with other major national harm reduction advocacy and consumer groups.

- **Ongoing research:** Positioning Japan as a best practice example for smoking cessation and integration of harm reduction methods into tobacco control for the prevention and control of smoking-related disease, disability, cost and premature death.

Embracing THR, cessation, and improved lung cancer treatment even more, represents a major opportunity for Japan to dramatically improve the health of their populations and demonstrate global health leadership.

2. Rationale

GLOBAL PROGRESS TO END SMOKING HAS STALLED

Current approaches to tobacco control have stalled. The World Health Organization (WHO) projects that 1.27 billion people globally will smoke by 2025[1], and that tobacco use will kill 8.7 million annually.[2] Deaths are projected by WHO to increase to 10 million in five years before declining to about 6.5 million by 2060.[3] This is not what public health success looks like.

Based on the WHO report on the global tobacco epidemic, 2023,[2] As seen in Figure 1, while Japan has a male smoking prevalence of 24.8%, the female smoking prevelance is only 6.2%.

This report aims to provide an alternative vision of what is possible. We consider the benefits of interventions based on tobacco harm reduction (THR) products, which include nicotine without the deadly exposures that cause the harms. As stated in a recent article by 15 past presidents of the Society for Research on Nicotine and Tobacco, ***"Nicotine is the chemical in tobacco that fosters addiction. However, toxic constituents other than nicotine, predominantly in smoked tobacco, produce the disease resulting from chronic tobacco use."*** [4]

These products include vapes, oral nicotine pouches, e-shisha and heated tobacco products. They are gaining traction by consumers but are not yet embraced by physicians and governments as key to cutting premature deaths. We also consider the benefits of better treatment for lung cancer, knowing it accounts worldwide for 2.5 million cases and 1.8 million deaths a year.[5]

Because the Japanese healthcare systems are as advanced in regularly updating its cancer diagnostic and treatment programs, the use of emerging technologies such as AI-assisted (artificial intelligence) diagnostics, might assist the country to address lung cancer in an even more effective manner.

WHO NEGLECTS THE LIFE-SAVING POTENTIAL OF TECHNOLOGICAL INNOVATION

The WHO Framework Convention on Tobacco Control (FCTC) is the first international treaty negotiated under the auspices of WHO. FCTC has led international control efforts for over two decades. Decisions taken at its governing body's 2024 gathering (known as COP10) focused on a variety of worthy issues, including environmental effects of tobacco cultivation and cigarette filters, and guidelines for tobacco advertising and media promotion.[6] However, COP10 did not have substantive, potentially life-saving discussions on tobacco harm reduction (THR). Nor did it address the role of innovation and technology improvements that could reduce tobacco harms, and the need to adapt policies as these become available.[7]

The omission of a focus on THR has two unfortunate implications. First, it perpetuates a view among public health experts that innovation and new technology is irrelevant to ending smoking. Second, it implies that equity in access to effective, life-saving technologies does not matter in tobacco control. That partly explains why access to nicotine replacement therapies (NRT) remains paltry across LMICs.[8] This is despite NRTs having been included on the WHO Essential Drug List in 2009.[9]

We have seen remarkable progress across the fields of biotechnology, pharmaceutical innovation and diagnostics led by private companies and supported in part by leading health research funders like the U.S. National Institutes of Health (NIH). The result is that a range of THR products have met the United States Food and Drug Administration (USFDA) criteria of being ***"appropriate for the protection of public health."*** [10] To date, the FDA has authorized marketing of 45 products, including 34 tobacco - and menthol-flavoured e-cigarette products and devices. They include four major categories: heated tobacco products, e-cigarettes, snus, and oral nicotine pouches.[11] All of them use nicotine. None involve combustion. All substantially reduce exposure to the toxic substances in combustible cigarettes.[12,13]

In the Middle East one new addition, a charcoal-free shisha, represents a unique potential contribution to tobacco harm reduction led by Middle East innovation.[13,14]

3. Benefits of Tobacco Harm Reduction (THR)

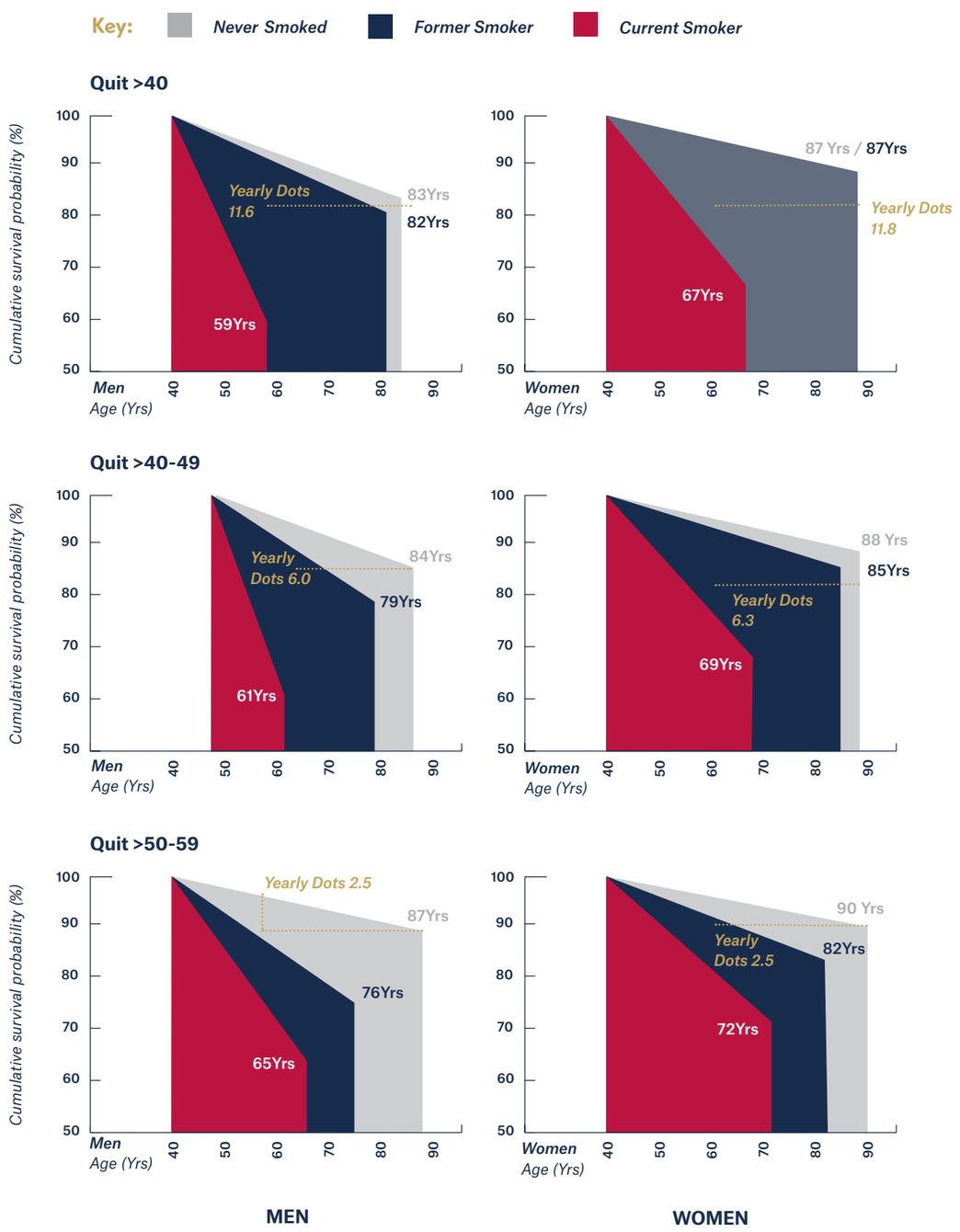
THE QUALITY OF EVIDENCE ABOUT THE BENEFITS OF THR FOR CESSATION AND HARM REDUCTION HAS STRENGTHENED

During 2024, leading medical journals have published views that support the value of smoking cessation and tobacco harm reduction.

Cho and colleagues, writing in NEJM Evidence[15], draw on four national cohorts involving 1.48 million people followed for 15 years to produce updated data on the benefits of adult cessation by age. They state that ***"Cessation at every age was associated with longer survival, particularly cessation before 40 years of age."***[15]

Cho et al. shows no differences in survival between men and women who never and formerly smoked before age 40, compared to a decade difference among those who quit between 50-59. Note that in the older age group, former smokers still show a decade advantage in survival compared to current smokers. No other public health interventions can achieve this for people at age 50.

Figure 3: Life expectancy gains by age in men and women
This figure shows an Illustrative model, based on the article by Cho et al, NEJM Evidence, 2024[18]



Pair this with a Korean study from JAMA Network Open, focused on cancer risk following cessation. Almost three million people were followed for over 15 years. Regardless of quitting age, a significant reduction in cancer risk was observed.[16]

The Lancet[17] and the New England Journal of Medicine[18] each recently carried articles calling for a greater focus on the value of THR for cessation. Beaglehole and Bonita (both previous directors of chronic diseases at WHO), writing in The Lancet, make the case for WHO to adopt THR to save lives. As they note, ***"The FCTC does not prohibit harm reduction approaches but leaves it up to countries to decide how to regulate e-cigarettes and other novel nicotine products."*** Further, ***"WHO's lack of endorsement of tobacco harm reduction limits healthier choices for the 1.3 billion people globally who smoke and who are at an increased risk of early death."***

Nancy Rigotti of Harvard Medical School, writing in the NEJM, suggests that we have reached a ***"tipping point"*** in the quality of trial evidence, that requires physicians to ***"acknowledge this progress and add e-cigarettes to the smoking cessation toolkit."***

Why does this matter for THR? Multiple studies, and Cochrane systematic reviews[19], conclude that e-cigarettes (vapes) are almost twice as effective as achieving cessation than NRTs. In short, current evidence suggests that e-cigarettes are the most widely available effective means for smokers to quit. Cho et al.'s comments in the NEJM about the benefits of smoking cessation at every age do not differentiate between cessation methods; they apply to quitting with THR products or with NRTs.

More studies are needed to thoroughly assess the effectiveness of snus, nicotine pouches, and heated tobacco products as cessation interventions. Further, there is a major gap in knowledge about how to reach those who smoke, who are older than 40 years of age, and smoke heavily (more than 20 cigarettes a day). The recent WHO guidelines on cessations ignore the potential health gains that addressing this group of smokers would achieve. They constitute about 20-25% of all adult smokers yet account for over 70% of all lung cancer and COPD cases. Manufacturers of THR products have also not addressed these smokers tending to focus on younger, lighter smokers.[20]

Table 1 shows the current state of play regarding clinical trials, cessation and all major THR categories. It shows that randomised clinical trials (RCTs) and solid evidence about the effectiveness of cessation is strongest from e-Cigarettes, research is underway in other categories. Given the significant consumer shift towards smokefree nicotine alternatives, Japan is well placed to carry out research in the heated tobacco product category, and across other THR categories as they become regulated and available for consumer use.

Table 1: Status of randomised clinical trials (RCTs) to assess the effectiveness of THR for cessation

E-CIGARETTES (VAPES) Several RCTs have been completed allowing for a continuously updated systematic review by the Cochrane Collaboration	**Electronic Cigarettes for Smoking Cessation - Lindson, N - 2024 | Cochrane Library**
ORAL NICOTINE POUCHES No systematic review Several studies are in progress	**Project 3: Randomized Placebo-Controlled Trial of Nicotine Pouches in Smokers - Penn State (psu.edu)**
	Clinical Study Protocol on Electronic Cigarettes and Nicotine Pouches for Smoking Cessation in Pakistan: A Randomised Controlled Trial - PMC (nih.gov)
	Using Pod Based E-Cigarettes and Nicotine Pouches to Reduce Harm for Adults with Low Socio-economic Status Who Smoke: A Pilot Randomized Controlled Trial | Nicotine & Tobacco Research | Oxford Academic (oup.com)
	JMIR Research Protocols - Biomarkers of Exposure and Potential Harm in Exclusive Users of Nicotine Pouches and Current, Former, and Never Smokers: Protocol for a Cross-Sectional Clinical Study
SNUS No systematic review but there are several completed studies	**Randomised Trial to Compare Smoking Cessation Rates of Snus, With and Without Smokeless Tobacco Health-Related Information, and a Nicotine Lozenge | Nicotine & Tobacco Research | Oxford Academic (oup.com)**
	Randomised Clinical Trial of Snus Versus Medicinal Nicotine among Smokers Interested in Product Switching | Tobacco Control (bmj.com)
	Randomised Clinical Trial of Snus Examining the Effect of Complete Versus Partial Cigarette Substitution on Smoking-Related Behaviors, and Bio-Markers of Exposure | Nicotine & Tobacco Research | Oxford Academic (oup.com)
HEATED TOBACCO PRODUCTS One study published with an update to 24 weeks being completed	**Comparing the Effectiveness, Tolerability, and Acceptability of Heated Tobacco Products and Refillable Electronic Cigarettes for Cigarette Substitution (Ceasefire): Randomised Controlled Trial - PMC (nih.gov)**

As mentioned, the United States' FDA has granted ***"modified risk tobacco product"*** status to some oral and heated tobacco products based on submitted scientific evidence.[21] Real-world evidence also exists, including meaningful reductions in cigarette smoking in countries such as Sweden and Japan due to switching to THR products.[22] Because these are newer technologies, we do not have studies on long-term effects of switching to THR products. In the meantime, we can look to the plethora of impressive studies using biomarkers of outcomes that have high predictive value for cancers, respiratory and heart disease.[23,24,25] These studies are used by companies in their USFDA applications and deserve to be cited and used more extensively by the public health community when motivating policy makers.

COUNTRY-SPECIFIC STUDIES OF LIVES SAVED ARE NEEDED TO DRIVE FOR NATIONAL CHANGE

Across diverse disciplines, there is a long history of using rigorous methods to provide data on alternative futures.[26] Such ***"foresight studies"*** provide policy makers and the public a compelling vision of a future that is better than the status quo and is possible through the application of knowledge and interventions available today. We apply such an approach to show that it is possible to influence the course of the tobacco epidemic.

4. Analysis of key indicators in Japan

Japan has a population of 127.7 million. 157,180 die prematurely every year from combustible tobacco and toxic smokeless tobacco products.[27] GDP per capita in Japan is $33,800. Life expectancy in Japan for men is 82.8 years and 88.1 years for women.[27]

Table 2: Demographic and development data for Japan

	Japan
GDP/capita in thousands $	**33.8**
Years of Educational Attainment (2021)	**13.3**
2021 Population in millions	**127.7**

2021 Life Expectancy (Males/Females)

MALES	**82.2**
FEMALES	**88.1**

Data source: population, schooling life expectancy source: IMHE country profiles. *https://www.healthdata.org/research-analysis/health-by-location/profiles*
GDP/capita source: World Bank *- https://data.worldbank.org/indicator/NY.GDP.PCAP.CD*

Table 3: Top five risks underpinning death, disease, and disability in Japan

Japan

Rank (2021)	
1	High Fasting Plasma Glucose
2	Tobacco
3	High Blood Pressure
4	Diet
5	High Body Mass Index

Data source: *IMHE country profiles*
https://www.healthdata.org/research-analysis/health-by-location/profiles

Table 3 shows that tobacco use features as one of the top two risks in Japan. Diet-related and clinical factors related to chronic disease feature strongly as major risks driving the burden of disease, with high blood pressure as the top risk.

Table 4: Smoking rates and numbers of smokers in Japan

Japan

Smoking Prevalence (%)	
MALES	24.8
FEMALES	6.2
WHO estimated 2025 prevalence	15.5
Japanese Survey Year	2022

Data source: *2022 National Health and Nutrition Survey Result (FMC and THP)*
https://www.mhlw.go.jp/stf/newpage_42694.html

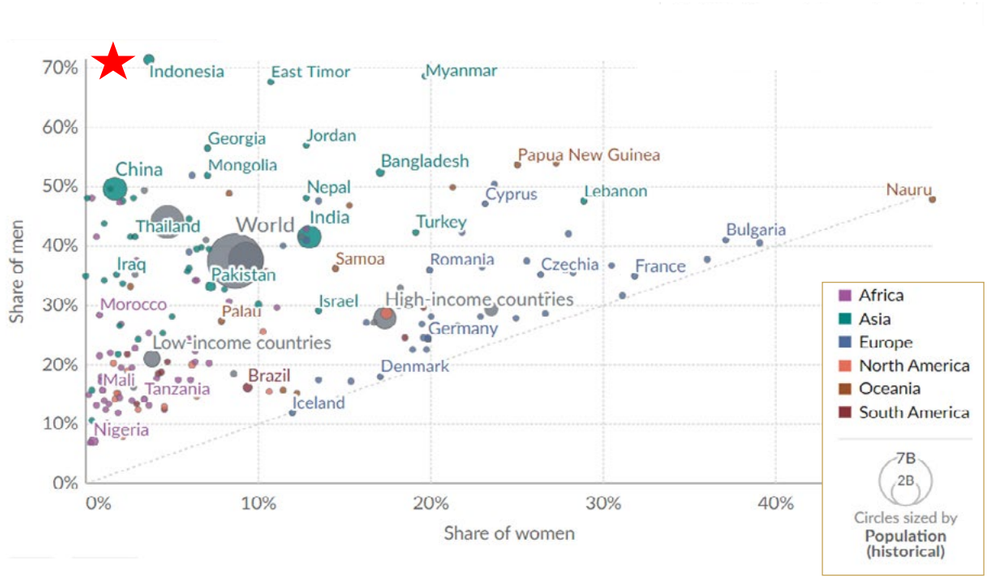
WHO estimates 2025 prevalence: *WHO global report on trends in prevalence of tobacco use 2000–2030 (https://www.who.int/publications/i/item/9789240088283)*

Note that there are large differences between the male and female smoking rate. In Japan, the male smoking rate is significantly higher than female smoking rates.

The opportunity to ensure that women maintain such low rates demands greater support to efforts to promote their behaviour as the desired social and health goals. Industry should be required to show that they are not marketing any tobacco or related products to women in much the same way they are required to do this for youth.

Figure 4: Smoking in men vs. women, 2020

The share of men versus the share of women aged 15 years and older who smoke any form of tobacco, including cigarettes, cigars, pipes or any other smoked tobacco products. Electronic cigarettes are not included.



Data source: *World Health Organization (Via World Bank)*

In Japan, the sale of e-cigarettes containing nicotine is prohibited unless they are approved as medicinal products, a status that, as of now, no e-cigarette has achieved. Consequently, only nicotine-free e-cigarettes are legally available for purchase in the country. These non-nicotine e-cigarettes are sold without specific regulations.

Table 5: Diversity of tobacco use and harm reduction products in Japan

Japan

Category	Product Examples	Prevalence in Japan	Public Health Concerns	Relation to Menthol Debates Globally
Cigarettes (Combustibles)	**Multiple brands**	Most common form of tobacco use, especially among men (24.8%)	High risk of smoking-related diseases such as lung cancer, cardiovascular disease	Menthol has been banned in countries such as the EU and the US due to its potential appeal to youth
Heated Tobacco Products (HTP)	**IQOS (5.7%), Glo, PloomTech (5.4%), GLO (2.6%), Other HTPs**	Introduced to the market as harm reduction products, with high uptake	Less harmful than combustible cigarettes, but still pose risks especially for nicotine dependence	Similar debates on the use of flavours could emerge, especially for its potential attraction for youth initiation and use
Snus	**Swedish snus brands and Zerostyle mint**	Legal for use and products can be marketed	Less harmful than cigarettes, but still pose risks	Similar debates on the use of flavours could emerge, especially for its potential attraction for youth initiation and use
Oral Nicotine Pouches	**Velo and Zyn are popular brands**	Licensed as a pharma product	Not documented	Not applicable
Nicotine Replacement Therapies	**All pharmaceutical brands allowed**	Permitted and marketing of these products allowed	Not applicable	Not applicable
E-cigarettes (non-nicotine)	**Vuse Go Vuse Go 700 Beyond Vape Japan (store)**	According to a panel survey on tobacco consumption conducted in Japan in 2022, only 0.5% of adults in Japan smoked nicotine-free e-cigarettes every day	Less harmful/risky than cigarettes and HTPs	Unlike the US and Europe, Japan currently has no intention of banning menthol-flavored tobacco products. An official from the Ministry of Health, Labour and Welfare stated that menthol is not seen as problematic in Japan

Data source: *Global State of Tobacco Harm Reduction (GSTHR) (2022)*, GSTHR reports provide an overview of the availability and use of harm reduction products such as nicotine pouches, heated tobacco, and e-cigarettes in various countries, including Indonesia.

Table 6: Top ten causes of death in 2021 in Japan (IHME). Those strongly related to tobacco are in bold

Japan

Rank (2021)	
1	Alzheimer's Disease
2	**Stroke**
3	**Ischaemic Heart Disease (IHD)**
4	**Lung Cancer**
5	Lower RI (Respiratory Tract Infections)
6	**Colorectal Cancer**
7	**Stomach Cancer**
8	**Chronic Kidney Disease**
9	**Pancreatic Cancer**
10	**Chronic Obstructive Pulmonary Disease (COPD)**

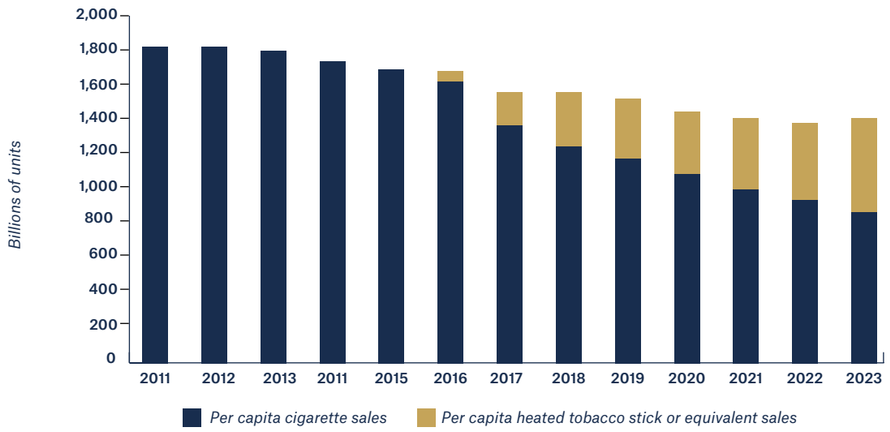
Data source: *IMHE country profiles. https://www.healthdata.org/research-analysis/health-by-location/profiles*

NOTABLY, 8 OUT OF THE TOP 10 CAUSES OF DEATH IN JAPAN IN 2021 WERE SMOKING-RELATED

Smoking is a major cause of chronic obstructive pulmonary disease (COPD), ischaemic heart disease (IHD), stroke, and cancer deaths. The table shows the importance of smoking as a risk factor in Japan, with eight out of the top ten linked to combustible tobacco product use. It also highlights other important risks: such as alcohol, diet and obesity. This triple burden of diseases strains the ability of health systems.

The dramatic decline in combustible cigarette sales, against the background of the availability of heated tobacco products, deserves thorough investigation. Cummings et al note that ***"Halving the cigarette market in Japan in just over a decade is a remarkable achievement and figuring out how to replicate this type of change elsewhere should be a priority for public health research. Clinical trials are needed to test if HTPs can help addicted cigarette smokers transition away from smoking."*** [28]

Figure 5: Per capita cigarette and heated tobacco stick or equivalent sales in Japan, 2011-2023



Smoking has a significant economic impact in Japan. The total cost is estimated to be around ¥6.99 trillion/US$45.44 billion annually[29]. This figure includes both direct costs, such as healthcare expenditures, and indirect costs, like lost productivity due to illness and premature death[1]. Although the decline in smoking rates over the past few decades has been notable, with adult smoking rates dropping from over 35% in the 1980s to below 18% today[29]. Despite this, the economic burden remains substantial due to the high costs associated with treating smoking-related diseases and the loss of productivity[29].

In a September 2024 article, Isao Kamae and Joerg Mahlich call for: ***"Japan should prioritize cost-efficient measures that promote public health and economic benefits. Encouraging smokers to switch to reduced-risk products, raising awareness of health risks, and adopting a harm-based taxation model can drive positive change. Public–private partnerships can further enhance harm reduction efforts. With a combination of tax reforms, revised regulations, collaborations, and ongoing research, Japan can create a more effective and comprehensive approach to tobacco control."*** [30]

Combined with inadequate national tobacco control, the slow progress of THR introduction, high physician smoking rates and health professional misperceptions of THR and nicotine[31], urgent action is required. Japan represents one of the most significant opportunities for the acceleration of tobacco control through THR.

In summary, tobacco-related disease, disability, premature death and its burden on the economy, positions Japan as a country of particular interest for global public health. Coupled with the unparalleled switch of combustible cigarette consumers to heated tobacco products, ongoing research is vital of the factors driving transformation and its potential public health gains.

Calculating the "size of the price": the aim

This study aims to provide national policymakers and public health experts with estimates of the value of THR, better cessation programmes, and improved access to lung cancer diagnostics and treatment in terms of measured as ***"lives saved"*** over the next three to four decades.

5. The Approach

We compare WHO projections of future tobacco deaths by 2060. These are based on continued and more effective implementation of the key components of the WHO Framework Convention on Tobacco Control (FCTC), simplified into six policy measures labelled collectively as MPOWER. Disappointingly, tobacco harm reduction (THR) was omitted from the MPOWER[32] approach. The WHO projections also leave out potential improvements in the effectiveness of cessation services, as well as access to rapidly improving diagnostics and treatments for lung cancer. We focus on lung cancer for two reasons. It accounts for 2.5 million of the 8.5 million tobacco deaths, and better diagnostics and treatment suggest that within a decade, lung cancer will no longer have a five-year survival of about 10-20% but approach the survival rate of breast cancer which has reached 90%.

Tobacco-related diseases are chronic conditions that take a few decades before the full benefits of cessation or harm reduction are visible in national data. This is a critical point to appreciate. Recent updates on the value of cessation (as described above) show that policy makers have overestimated how long it takes to achieve benefits from adult cessation: in terms of reduced overall mortality and in deaths from major tobacco related cancers.

All the expected premature tobacco deaths by 2060 will occur in current adult smokers. If no person under 18 years of age started smoking today, lives saved among youth would take until the 2060s to become visible in national mortality data. This reinforces the need to focus on the behaviours of middle-aged smokers and users of toxic smokeless tobacco products, if we seek population health gains within the next several decades. Many of these smokers will be in touch with health services for early-stage COPD, heart disease and possible cancer. This creates opportunities for secondary prevention.

RECENT APPROACHES TO ESTIMATING "LIVES TO BE SAVED"

There have been several recent efforts to model responses to the question: ***"What would happen to the burden of disease if countries did embrace THR?"*** These have been published by academics and industry. We refer readers to our earlier report to obtain details on **Lives Saved: Integrating Harm Reduction for Tobacco Control in Brazil, South Africa, Bangladesh, Kazakhstan, Pakistan, Czechia, Indonesia, Nigeria and Kenya** and the "**Saving Lives like Sweden"** reports.[33]

WHY THIS STUDY IS IMPORTANT NOW

This study comes at a time when over a billion people smoke and THR products are used by 120-140 million people globally. Most people who use THR products live in high income countries. In these countries we now have powerful evidence of the impact of THR use on the declining use of combustibles. This has been well described for countries such as Sweden, UK, Japan, and USA.[34] We believe that when faced with a clear choice of policies, responsible governments will act to save lives and be supported by civil society.

METHODS

The approaches used by seasoned ***"modellers"*** were reviewed and simplified to their essential elements. Details are contained in earlier reports. The key assumptions are repeated below.

ASSUMPTIONS

The following **assumptions** are made in calculating lives saved.

- **At present, NRTs are 10% effective in terms of cessation at one year. Vapes are twice as effective.**
- **The spectrum of THR products reduce toxic exposures by 80% and reduce smoking-related causes of premature death by 70%. These conservative values for comparability are used knowing the emerging evidence from exposure assessments and the use of bio-markers of outcome, show that far greater levels of reduced harm are likely.**
- **Lung cancer survival at five years will increase to 50% for most countries by 2050 driven by improvements in diagnosis and treatment.**
- **WHO estimates that cessation services (a mix of medications and behavioural support) will be 50% effective in achieving one-year quit rates by 2035 and be available to 50% of smokers by 2045. This effectiveness projection is not aligned with research findings, but for the purpose of this study, it has been accepted as a "best case assumption".[35]**
- **The rate of decline in smoking will accelerate from 2035 onwards, which will lead to health impacts increasing sharply from 2045 onwards.**
- **WHO trends suggest that from 2000 to 2025 smoking rates will fall by a third in men. We believe this could accelerate to 50% from 2030 in all countries.**

ESTIMATES FROM ABOVE ARE USED TO MODEL THREE SCENARIOS

SCENARIO 1: Status quo (traditional tobacco control). Current trends using WHO estimates. The WHO estimate of a 35% decline in global tobacco deaths from the peak of 10 million[3] is used as the basis for calculating country-specific estimates.

SCENARIO 2: Tobacco control + Implementation of THR policies and availability of THR products. Trends that include THR uptake assuming that, as a group, they will lead to a 56% decline in tobacco deaths and will become available increasingly from 2035.

SCENARIO 3: Tobacco control + THR uptake + Improved access to diagnostics and treatment of tobacco-related diseases. Trends that include THR and better access and use of diagnostics and treatments (focused mainly on lung cancer, which killed an estimated 1.8 million people in 2020).[36]

The differences between the WHO projections and those where THR alone, and THR with other measures were calculated assuming a linear relationship between lives saved over the decades.

NOTE ABOUT THE QUALITY AND AVAILABILITY OF DATA

The quality of evidence used to develop THR policy needs to be methodologically sound. Polarization within the field of tobacco and nicotine science threatens the integrity of research.[37] Recent reviews of epidemiological and toxicological research related to THR have highlighted a range of basic concerns about methods used.[38,39,40,41]

Common issues include unclear hypotheses or methods not appropriate to test stated hypotheses; unsupported claims of causality; not controlling for potential confounding variables; amounts of product exposure not standardized or specified; non-representative study participants; and not considering effects of participants' previous combustible tobacco use.

Laboratory studies testing new technologies (such as vaping and heated tobacco devices) often use poorly reported or non-reproducible methods, under conditions incompatible with real-world use. Some papers have been formally retracted. Unfortunately, critiques and retractions cannot stop sloppy or slanted science from being repeatedly cited and potentially misleading policy makers, physicians and consumers.

6. Potential Lives Saved by THR in Japan

Table 7 contains the output of the expert analysis to calculate the number of lives to be saved between 2020 and 2060 if THR and related measures are implemented. These numbers represent the additional gains, beyond those WHO estimates, that will occur because of the roll-out of MPOWER. They represent a significant number of premature deaths. Two scenarios are listed: the first includes accelerated access to THR products, while the second also includes better access to more effective nicotine replacement therapies (NRTs) and better access and treatment of lung cancer.

These numbers are indicative of what could happen if governments, health professionals, industry and consumers aligned on policies and actions. Failure to do so will leave the WHO projection in place. It was beyond this report to calculate the impact on disease and disability or the economic benefits of THR. That requires a separate, more detailed set of analyses ideally led by countries.

Note that there is growing body of evidence that shows that nicotine itself could well be beneficial for a range of neurological conditions[42,43] of which Parkinson's Disease is a notable one. This disease is projected to have a major devastating impact across all countries over the next decades.[44] Better treatments are therefore a high priority. Of the lives saved using a background of no action, 50% will occur due to MPOWER strategies and an additional 50% due to THR, better cessation, and management of lung cancer.

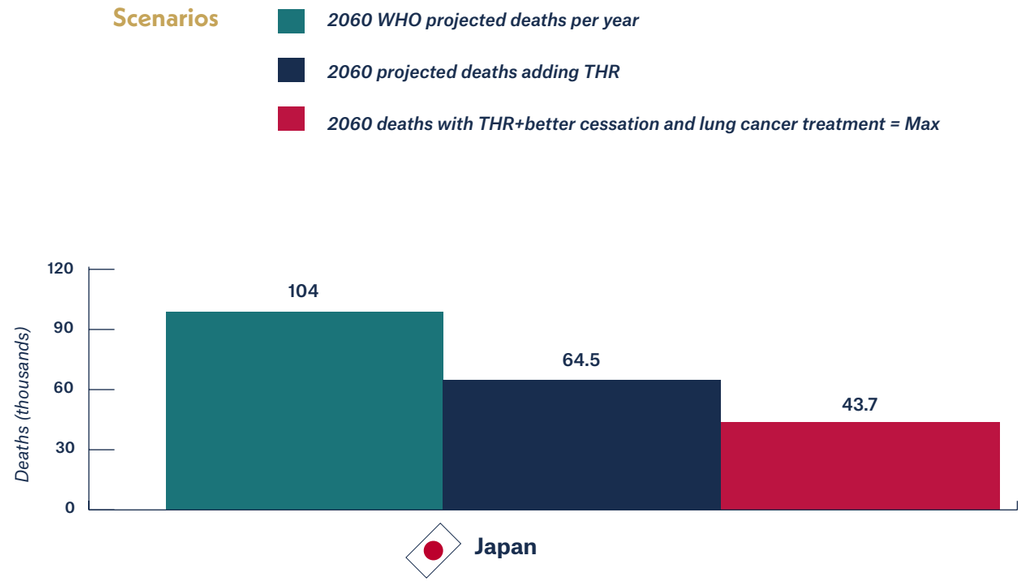
Table 7: Smoking related deaths and lives saved from 2020-2060 through tobacco harm reduction, better cessation, and lung cancer treatment

Japan

Annual Deaths from Tobacco (Thousands)	
2019	157.0
2060 WHO projected deaths per year	104.0
2060 projected deaths adding THR	64.5
THR+better cessation and lung cancer treatment = Max	43.7
Lives Saved	
2020 - 2060 total deaths - THR	1,580,000
2020 - 2060 total deaths - THR plus cessation	2,040,000

Figure 6: Projected deaths from tobacco in 2060

This figure shows the number of tobacco deaths expected to occur in 2060 using three scenarios: WHO projections using FCTC and MPOWER measures; WHO projections adding THR products; and WHO projections adding THR, smoking cessation and, lung cancer innovations.



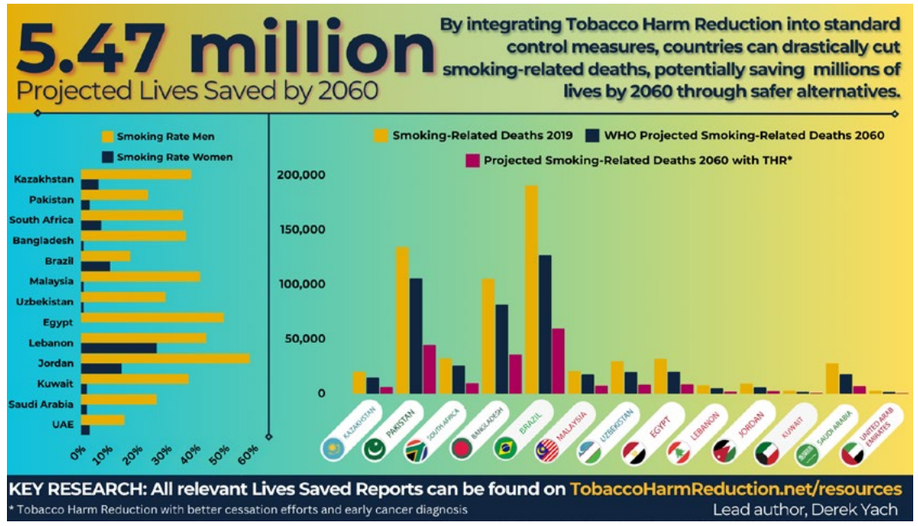
2.04
MILLION

A total of 2.04 million lives could be saved in Japan if all tobacco harm reduction products were made widely available, accessible and affordable and if better cessation services were developed, and if better treatment for lung cancer was introduced over the next four decades. This represents a major opportunity for Japan to improve the health of their populations.

7. Potential Lives to be Saved in other countries

Along with the report on Japan, our reports show that by integrating tobacco harm reduction into traditional tobacco control measures, countries can drastically cut tobacco-related deaths. Millions of lives can potentially be saved through less harmful smoke-free nicotine alternatives. The countries shown in Figure 7 include a population of 897 million people, with a significant number of adults who smoke. If these countries were to embrace THR, better cessation, and more effective treatment for lung cancer, we estimate that 5.47 million lives would be saved over the next decades. Note these are over and above lives to be saved by continuing with WHO's current programs alone.

Figure 7: Potential Lives Saved by Integrating THR into Tobacco Control



WHAT ACTIONS ARE NEEDED IF WE ARE TO SAVE LIVES?

Key actions needed include:

- **Activating health professionals (especially physicians)** to communicate the benefits of THR to patients in all clinical encounters, to counter disinformation about nicotine and the value of THR, and to develop national equivalents of the Royal College of Physicians report on THR and vapes.

- **Encouraging risk-proportionate regulation:** Governments should continue to revise regulations to improve access to less harmful nicotine / THR products and invest in national science and research to advance THR. Cigarettes should be substantially more heavily regulated and taxed than reduced risk products. That makes it easier for consumers to switch and improve their health.

- **Governments investment in national science and research.**

- **Strengthening consumer representation:** Creating and strengthening independent, science-based consumer groups able to advocate for their needs, based on sound science.

Embracing THR, cessation, and improved lung cancer treatment represents a major opportunity for Japan to dramatically improve the health of its populations.

A. Activating health professionals.

Health professionals, physicians in particular, need to be activated to counter disinformation about nicotine and the value of THR, to communicate the benefits of THR to patients in all clinical encounters. Drawing on the groundbreaking approaches used 60 years ago by the Royal College of Physicians, they should help lead policy development by publishing a major report on the state of smoking and the role of THR in preventing and controlling tobacco-related disease, disability and premature death.

PHYSICIANS SHOULD COMMUNICATE THE BENEFITS OF THR TO PATIENTS AND COUNTER DISINFORMATION

Physicians led in the early years of tobacco control in the UK and the USA. They were the subjects of the earliest cohorts that showed that smoking kills.[45] They galvanised reports[46] that led to the first government actions. Doctors quit in large numbers once they understood the evidence, though this varied by region.[47] They started cessation services for their patients, and they led the development of public health policies to end smoking.

A new 16-country survey on trust and health[48], found that physicians remain the most trusted source of information. Physicians can be at the forefront of accelerating the demise of smoking and reducing tobacco-related disease, disability, and death – if encouraged to communicate harm reduction strategies to their patients. This needs to start with correcting the massive extent of disinformation. In a 2022 survey of 15,335 physicians in 11 countries, 77% incorrectly believed that nicotine causes lung cancer.[49] However, on average over 80% of physicians were at least moderately interested in receiving training in cessation and THR.[50]

In Japan, 89% of physicians surveyed incorrectly believed that nicotine causes atherosclerosis (89%), lung cancer (88%), COPD (88%), head, neck and gastric cancers (87%), bladder cancer (85%) and birth defects (71%). More studies to identify the distinctive perceptions and knowledge of doctors in Japan are needed. It is encouraging that 90% of physicians are interested in taking training on how to help their patients who smoke combustible tobacco products to quit smoking.

PHYSICIANS SHOULD ADDRESS MISSED OPPORTUNITIES FOR SECONDARY PREVENTION AMONG PATIENTS WHO SMOKE

Millions of people are diagnosed with conditions such as COPD, IHD, early-stage cancer, stroke, other tobacco-related diseases, and schizophrenia every year in Japan. Over 70 percent of people with several of these conditions smoke at the point of diagnosis. A year or two after diagnosis, international research suggests that most still smoke. Tobacco cessation is either not attempted or fails. This accelerates clinical decline and substantially adds to the burden of disease and suffering experiences by patients. Physicians should review national data on this and implement programs that give high priority to cessation and access to harm reduction at every clinical encounter.

MEDICAL AND HEALTH EXPERTS SHOULD BE ENCOURAGED TO DEVELOP A NATIONAL EQUIVALENT OF THE ROYAL COLLEGE OF PHYSICIANS REPORT ON E-CIGARETTES AND HARM REDUCTION

Over 60 years ago[51] the Royal College of Physicians (UK) published the first major report on the harm of smoking. Their voice over the decades has led policy development in the UK and around the world. Earlier this year they released their latest evidence review on e-cigarettes and harm reduction.[52] It is led by physicians and is meant to aid physicians in ***"how e-cigarettes can be used to support more people to make quit attempts while discouraging young people and never-smokers from taking up e-cigarette use."*** Equivalent reports for Japan, that was led by prestigious medical societies and academies could galvanise needed action. Ideally, this should be a project-endorsed and facilitated by the Ministry of Health.

B. Governments should continue to revise and establish risk-proportionate regulation, to improve access to THR products and invest in national science and research to advance THR.

The Japanese government should be encouraged to regulate alternative nicotine products proportionate to the risk they pose to health and in ways that maximise benefits and make healthier choices as easy as possible.

Preferably, the Government's regulatory progress needs to be accompanied by extensive and continuous communications programs that engage leaders in healthcare and adults who use tobacco products. The regulations should aim to balance consumer access with public health concerns, particularly focusing on preventing youth uptake while allowing adult smokers access to THR alternatives.

Good regulatory practice needs to be studied. For example, the United Kingdom approach aimed at cutting social class gradients in adult smoking through the use of THR products.[53] In this world-first government-sponsored scheme, smokers are urged to swap cigarettes for vapes in a ***"Swop to Stop Scheme."***

C. Governments investment in national science and research.

Most publicly funded research on THR is carried out in the US, Europe and exported worldwide. Local investment in science and scientists has three effects: it ensures that locally relevant research is developed, it leads to the creation of local expertise and building local expertise in science leads to better informed local policies and policy makers. This has been true in all successful areas of health and science. One example of the neglect of THR research in Japan is that it has recorded 200 citations of local research per million smokers over the last decade, compared to about 500 citations per million smokers in the USA, UK and New Zealand. This hampers local innovation and limits 'policy makers' ability to make fully informed decisions.[54]

D. Creating independent science-based consumer groups able to advocate for their needs.

HIV/AIDS patients and advocates rallied for better policies under the banner of ***"nothing about us, without us."*** This led to changes in government policies that included a commitment to harm reduction and led to better access to antiretrovirals. As a result, millions of people are living longer and healthier lives across LMICs. Similar progress could follow if we had effective new nicotine user groups around the world.

While there are many active nicotine user groups around the world, they have yet to galvanise into a movement with impact. Their advocacy to highlight that tobacco-related deaths can be prevented, according to this study, is a much-needed element.

In Japan, there are a limited number of not-for-profit organisations or alliances that support harm reduction as a key public approach to addressing several major health issues-from alcohol and drugs, to HIV/AIDS and tobacco. These include the Japan Society for Tobacco Control (JSTC), involved in various initiatives to reduce smoking rates and promote harm reduction strategies. They focus on public education and policy advocacy to support healthier alternatives to smoking.[55] The **Japan Cancer Society** primarily focuses on cancer prevention, but also supports tobacco harm reduction as part of its broader mission to reduce cancer incidence and mortality[55]. There are also regional alliances actively involved in THR research and education, especially amongst health professionals and consumers, for example the **Asia Harm Reduction Alliance** (ASHRA).[56]

These organizations work towards reducing the harm caused by tobacco use through education, advocacy, and promoting safer alternatives.

8. About the Authors

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Dr. Yach is a former employee of the World Health Organization and of PepsiCo.
He received his MBChB from the University of Cape Town in 1979 and his MPH from Johns Hopkins School of Public Health in 1985. In 2007, he received an honorary DSc from Georgetown University. For several years Yach led major national epidemiological initiatives in South Africa. Yach then served under Director-General Gro Harlem Brundtland, as a cabinet director where he worked on the WHO Framework Convention on Tobacco Control and the Global Strategy on Diet and Physical Activity. He led global health at Yale School of Public Health and then at the Rockefeller Foundation before becoming SVP for Global Health and Agriculture Policy at PepsiCo. After 5 years developing and leading the Vitality Institute for Prevention in New York, he founded and led the Foundation for a Smoke Free World. Currently Yach is an independent global health consultant focused on ending smoking, supporting mental health and promoting healthy diets. He has served on advisory boards of the World Economic Forum, Clinton Global Initiative, and Wellcome Trust.[57]

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Dr. Delon Human is a specialist family physician, global health advocate, published author, international speaker and healthcare consultant specialising in global health strategy, harm reduction and health communication. He is the former Secretary-General of the World Medical Association, International Food and Beverage Alliance and Co-founder of the African Harm Reduction Alliance (AHRA). He has acted as an adviser to three WHO Directors-General and to the UN Secretary-General on global public health strategies.[59]

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Professor Marewa Glover is one of New Zealand's leading tobacco control researchers. She has worked on reducing smoking-related harm for 31 years. She is recognised internationally for her advocacy on tobacco harm reduction; and locally was a Finalist in the New Zealander of the Year Supreme Award in 2019 recognising her contribution to reducing smoking in NZ. In 2018, Dr. Glover was appointed Tobacco Section Editor for the Harm Reduction Journal. In that year she also established the Centre of Research Excellence: Indigenous Sovereignty & Smoking, an international programme of research aimed at reducing smoking-related harms among Indigenous peoples globally. The Centre's research was funded with a grant from Global Action to End Smoking (formerly known as Foundation for Smoke-Free World), an independent, U.S. nonprofit 501(c)(3) grant making organisation, accelerating science-based efforts worldwide to end the smoking epidemic. Professor Glover contributed to this report independently.[60]

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A full professor of internal medicine at the University of Catania with a specialist role as a respiratory physician, clinical immunologist, allergist and rheumatologist, Polosa is also the founder of the Center for Tobacco Research at the University of Catania, where contracted research staff conduct high-profile clinical and behavioural research. The focus of his academic research has been historically centred upon the investigation of mechanisms of inflammation, biomarkers of disease activity, and novel drug target discovery in respiratory medicine (asthma, COPD, rhinitis) and clinical immunology (allergic and autoimmune diseases). This has culminated in the participation of his research group in large EU-funded Pan-European research consortia. Nonetheless, over the last 15 years, his main research interest has progressively shifted in tobacco-related diseases, smoking prevention and cessation, tobacco harm reduction and e-vapor products.

More specifically, he has been involved in the behavioural, clinical, physiological and toxicological evaluation of e-cigarettes for over 10 years. He was the project lead of the first RCT in the world about effectiveness and tolerability of e-cigarettes (the ECLAT study), he is the most prolific author in the field of e-cigarettes, according to recent bibliometric research. He is a member of the Scientific Committee of LIAF (Italian Anti-Smoking League) and of INNCO (International Nicotine Consumer Organization). Already national coordinator for the Italian Working Group on electronic cigarettes and e-liquids, he has been elected convenor for the European Working Group on requirements and test methods for emissions of electronic cigarettes within the European Committee for Standardization (CEN/TC 437).[61]

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DR. ANDERS MILTON - SWEDEN

Dr. Anders Milton is a physician with extensive experience in public service, a highly sought-after consultant in the healthcare sector and a former chair of the WMA. Currently the owner and CEO of Milton Consulting, chair of the Snus Commission and chairman of the board of three foundations that work with education for children and adolescents and several for-profit companies in the field of life science. Dr. Milton's resumé also includes stints as President and CEO of the Swedish Medical Association (SMA), and as President of the Swedish Red Cross, the People and Defence Foundation and the Swedish Confederation of Professional Associations (SACO).[63]

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Dr. Diego Verrastro is a general surgeon, specialising in emergency medicine, abdominal mini-invasive surgery, ultrasonography and obesity. He is also spokesperson for RELDAT, The Latin American network for the reduction of tobacco-associated harm. In this role, he has called for further discussion of the merits of harm reduction in Latin America, drawing attention to the examples provided by other countries-including the UK, New Zealand and Sweden.[66]

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Prof. Stöver is a social scientist and Professor of Social Scientific Addiction Research at the Frankfurt University of Applied Sciences in Germany, Faculty of Health and Social Work. Since 2009 he has been the director of the Institute of Addiction Research. Heino Stöver's main fields of research and project development expertise are health promotion for vulnerable and marginalised groups, drug services, prison health care and related health issues (especially HIV/AIDS, Hepatitis C, drug dependence, and gender issues), and the potential of e-cigarettes. His international research and consultancy expertise includes working as a consultant for the European Commission, United Nations Office on Drugs and Crime (UNODC), World Health Organization (WHO), European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), International Committee of the Red Cross (ICRC) and Open Society Institute (OSI) in various contexts.[67]

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Dr. Anoop Misra is an Indian endocrinologist and a former honorary physician to the Prime Minister of India. He is the chairman of Fortis Centre for Diabetes, Obesity and Cholesterol (C-DOC) and heads, National Diabetes Obesity and Cholesterol Foundation (NDOC). A former Fellow of the World Health Organization at the Royal Free Hospital, UK, Misra is a recipient of the Dr. B. C. Roy Award, the highest Indian award in the medical category. The Government of India awarded him the fourth highest civilian honour of the Padma Shri, in 2007, for his contributions to Indian medicine.[68]

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PREVIOUS REPORTS:
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