LIVES SAVED



REPORT

INTEGRATING HARM REDUCTION INTO TOBACCO CONTROL

How many lives could be saved by accelerating tobacco control policies in Brazil?





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Executive Summary

Current global approaches to tobacco control have failed to halt the devastating toll of tobacco-related deaths, with the World Health Organization (WHO) estimating 8.5 million annual tobacco-related deaths, projected to increase to 10 million before slowly declining. A recent Scorecard assessed progress made by the FCTC on the eve of COP10, using WHO reports, and concluded that failed policies and underinvestment hampered progress.

This report addresses the pressing issue of tobacco control policies and their impact on health outcomes in Brazil. It builds on related reports addressing four other Low-Middle Income Countries; Kazakhstan, Pakistan, South Africa and Bangladesh; The key methods used in the past reports have been used here to assure comparability and where necessary, adjustments have been made.

In Brazil, there have been over two decades of steady progress implementing key FCTC measures. However, progress has slowed. In addition, tobacco-related causes, including heart disease, chronic obstructive pulmonary disease (COPD), stroke, and to a lesser extent lung cancer and tuberculosis (TB), are among the leading causes of death.

The report aims to provide policymakers and public health experts with estimates of the potential benefits of tobacco harm reduction (THR), improved cessation, and better access to lung cancer diagnostics and treatment to reduce premature deaths. It notes that alcohol use and abuse is extremely high and has negative synergistic effects with tobacco requiring integrated control.

The study considers the crucial role of time in addressing tobacco-related diseases, emphasizing that

the benefits of cessation or harm reduction take a few decades to fully manifest and that youth restrictions take 4 to 5 decades to show benefits.

All premature tobacco-related deaths by 2060 will occur in current adult smokers, underscoring the need to focus on middle-aged smokers and users of toxic smokeless tobacco products.

Recent modelling efforts have demonstrated the potential health gains from the adoption of THR products, including e-cigarettes, oral nicotine pouches, snus and heated tobacco products. This report builds upon their work.

The study's key findings indicate that significant lives can be saved in Brazil through the widespread adoption of THR and related measures. For instance, Brazil could prevent 1,364,000 premature deaths in the next four decades.

This report demands several actions. Before COP11 Member States need to activate the harm reduction provisions of the WHO Framework Convention on Tobacco Control (FCTC). WHO needs to be held accountable for supporting policy positions that undermine population health. Governments need to regulate nicotine products proportionate to the risk they pose to health. Physician leadership is needed to better support their patients and policymakers about the benefits of THR. THR users need to galvanise into a powerful movement that advocates pro-THR policies. Serious investment in LMIC capacity building in science and innovation is needed. Industry needs to step up THR activities in LMICS and consider developing products that meet medical licensing approval.





CHAPTER 1

Rationale

GLOBAL PROGRESS TO END SMOKING HAS STALLED

Current approaches to tobacco control have stalled. WHO projects that there are globally 1.27 billion smokers who die at a rate of 8.5 million annually from tobacco use. (1) That figure is projected by WHO to increase to 10 million in five years before declining to about 6.5 million by 2060. (2) This is not what public health success looks like.

New interventions based on THR products, which include nicotine without the deadly exposures that cause the harms, are rapidly gaining traction but are not yet embraced as key to cutting premature deaths. Further, advances in earlier diagnoses and better treatment for major tobacco outcomes are improving survival, mainly in higher income countries. We need better ways to save lives.

Global trends in tobacco use and its health impacts have recently been updated in WHO reports. (3) They build on trend analyses carried out by the Institute for Health Metrics and Evaluation (IHME) from 1990 to 2019. (4) From a macro perspective, tobacco use remains the largest preventable cause of premature death, accounting for 8.5 million deaths every year. Most of these deaths occur in LMICs, with almost 3.6 million premature deaths occurring in China and India alone. (5, 6)

WHO HAS NEGLECTED THE VALUE OF TECHNOLOGY INNOVATION FOR HEALTH IN UPDATING PROSPECTS FOR TOBACCO CONTROL

The COP10 Scorecard (13) highlights the reality that the WHO FCTC does not mention the role of innovation, technology improvements, and the need to adapt policies as these become available. This is notable when looking at Brazil. The Brazilian government, and their lead trade ambassadors and Foreign Minister during the FCTC negotiations (Celso Amorim who first led the FCTC negotiations, and Luiz Felipe de Seixas Correa who completed the negotiations) guided development of the FCTC while simultaneously leading the Doha Round on trade negotiations at World Trade Organization (WTO) where patents and intellectual property issues were leading issues led by the efforts to lower the price of HIV/AIDS drugs.

The fact that WHO's first treaty ignored this has had two implications: it has perpetuated a view among public health experts that persists today that innovation and new technology are irrelevant to ending smoking, and secondly, that equity in access to effective live saving technologies did not matter with regards to tobacco control. That partly explains why access to NRT remains paltry across LMICs. These issues are the most contentious ones under intense debate as WHO struggles to gain adoption of its second treaty addressing pandemics.

Brazil has been a very loyal WHO supporter since the second WHO Director-General was Brazilian (Marcolino Gomes Candau) When WHO takes a position (like opposing THR), it becomes tough to oppose it despite having a history of geopolitical independence in many other areas.





In sharp contrast to the neglect of innovation by public health 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 National Institutes of Health (NIH). The result is seen in terms of a range of THR products that have met the United States Food and Drug Administration (USFDA) criteria of being "appropriate for the protection of public health. They include four major categories: heated tobacco products, e-cigarettes, snus and oral nicotine pouches. This

report does not distinguish between them. In addition, there have been advances in developing new ways to address smoking cessation, early diagnosis of cancers, and more effective treatments for cancers, COPD, and heart disease.

This progress is set to continue and provides new hope and practical tools needed to reduce the current trends and impact of tobacco use. We take a forward-looking view of a future where innovation will cut premature deaths in this field, as it has across most of health and medicine.

THE QUALITY OF EVIDENCE ABOUT THE VALUE OF CESSATION AND HARM REDUCTION HAS STRENGTHENED

Table from Article titled Smoking Cessation and Short- and Longer-Term Mortality.

Table 1:

Years of Life Expectancy Gained between 40 and 79 Years of Age in Relation to Duration of Quitting Smoking by Sex and Cause of Death.*

	Former Smokers vs. Current Smokers by Duration of Quitting, yr		Never Smokers vs. Current Smokers, yr	
Cause of death	Men	Women	Men	Women
	<3	‡10	<3	‡10
All causes	5.5	9.9	5.1	9.6
Vascular disease	7.0	12.1	5.2	9.4
Cancer	4.5	8.2	4.6	8.7
Respiratory disease	7.5	12.3	9.9	15.1

^{*} The data were derived from life table estimates based on death rates adjusted for age, education, body mass index, and alcohol consumption (except in Norway).

Leading medical journals have recently revised their views on the value of smoking cessation and THR based on massive new studies.

Cho et al writing in NEJM Evidence (8) draws 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. Cessation at every age was associated with longer survival, particularly cessation before 40 years of age.

The table above (8) shows no differences in survival between never and former smokers at age 40, compared to a decade difference among those who quit





between 50-59. Note that in this age group former smokers still show a decade difference in survival compared to current smokers. There are no other public health interventions that achieve this for people at age 50.

This study needs to be read alongside a Korean study that focused on cancer risk following cessation. Almost 3 million people were followed for over 15 years. Regardless of quitting age, a significant reduction in cancer risk was observed. (11)

Why does this matter for THR? Multiple studies, including all Cochrane reviews, conclude that vapes are twice as effective in achieving cessation than NRTs-making, them the most widely available means for smokers to quit.

Both the Lancet and NEJM recently carried editorials and 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, made the case for WHO to adopt THR to save lives. (22) Nancy Rigotti writing in the NEJM asks whether we have reached a "tipping point" in the quality of evidence that now required physicians to advise their patients who smoke about the benefits of vapes. (25)

COUNTRY-SPECIFIC STUDIES OF LIVES SAVED ARE NEEDED

This study focuses on Brazil where a total of 191 000 people die prematurely every year of combustible tobacco and toxic smokeless tobacco products. Brazil has many competing priorities for health. Very high levels of alcohol use, obesity and unhealthy diets are reflected with tobacco use in their major causes of preventable deaths. As with some other middle income countries, it is characterized by having weak enforcement capacity of government regulations and have severe understaffing of the health sector. This is clearly seen in terms of their very high levels of illicit cigarette use. Current estimates place this as 36% of all cigarettes sold in Brazil. (21)

In Brazil, smoking rates are high among men and there is a modest gap between smoking rates and related deaths among men versus women (Table 2).

CALCULATING THE "SIZE OF THE PRIZE"

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 premature deaths prevented.

THE APPROACH

We compare WHO projections on future tobacco deaths that are based on continued and more effective implementation of MPOWER. (9) This excludes all forms of THR at present. Their projections also ignore potential improvements in the effectiveness of cessation services as well as access to rapidly improving diagnostics and treatment for lung cancer. We focus on lung cancer for two reasons. It accounts for 2.2 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. (10)

TIME MATTERS

In this study, we paid serious attention to the role of time. It is stressed here that since 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 (see above) shows that policy makers have overestimated how long it takes for the benefits of adult cessation to become visible in terms of reduced overall mortality and deaths from major tobacco-related cancers. (8)

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 data. This reinforces the need to address the needs of middle-aged smokers and users of toxic smokeless tobacco products today, if we seek health gains within the next three decades.





CHAPTER 2

Recent approaches to estimating "LIVES TO BE SAVED"

There have been several recent efforts to model responses to the question: "What if countries did embrace THR?". These have been published by academics and industry. We refer readers to our earlier report to obtain details. (12)





CHAPTER 3

Why this study is important now

This study comes at a time when THR products are used by 112 million people globally. (17) Most 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 (Sweden, UK, Japan, Lithuania, USA) (18) and early evidence from Pakistan (19) on the impact of nicotine pouches on the use of toxic smokeless tobacco products. Sweden has the most extensive data on the implication of this transformation for life expectancy and specific tobacco-related health outcomes. Newer projections have quantified the millions of lives to be saved through use of THR in LMIC and high-income countries (references to initial report plus UK, Canada.)

This study comes after the conclusion of COP10. Preceding the meeting we completed a Scorecard on progress made on the major provisions of the FCTC. (13) It highlights major gaps that limit progress to end smoking. Several issues raised in the report were incorporated into actions the WHO and Parties are required to take before COP11. This includes a review of the evidence of the benefits and risks of THR and investing in the financial needs of LMICS. This report provides some response to these issues and shines a light on the potential for THR to have major beneficial impacts on premature deaths and, implicitly, the quality of life in Brazil.

DEMONSTRATING PUBLIC HEALTH BENEFITS IN LMICs

To determine likely declines in premature deaths from tobacco use in Brazil between 2030 and 2060, we need to assume that there would be an increased awareness and use of THR, better diagnosis and greater access to more effective cessation services and treatment of lung cancer.



CHAPTER 4

Methods

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

4.1 Assumptions

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

- At present, NRTs are 10% effective in terms of cessation at one year. Vapes are twice as effective.
- The spectrum of THR products reduces toxic exposures by 80% and reduces tobacco-related causes of premature death by 70%. We use these conservative values for comparability, knowing that the emerging evidence from exposure assessments and the use of biomarkers of outcome are likely to show far greater levels of reduced harm.
- 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 is an ambitious projection, but for the purpose of this study, this has been accepted as a "best case assumption".
- The rate of decline in smoking will accelerate from 2035 onwards, which will lead to health impacts increasing sharply from 2045 onwards (see Figure 1).
- WHO trends suggest that from 2000 to 2025 smoking rates will fall by a third in men in Brazil.
 We suggest this could accelerate to 50% by 2030 in all countries. (3)

4.2 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. These trends 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-re-

lated diseases. Trends that include THR and better access and use of diagnostics and treatments (focused on lung cancer, given that it kills 1.8 million people a year (24)). Assumptions listed above are used.

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. Figure 1, however, shows that this is more likely to follow an inverse S shape with deaths accelerating beyond 2040. The cumulative number of deaths is not significantly affected by using linear extrapolation.





CHAPTER 5

Key data from Brazil

Table 2:

Country demographics and epidemiology (7)

Criteria	Brazil
Population (in millions)	216.7
Life Expectancy (1990, Males)	63.8
Life Expectancy (2017, Males)	72
Life Expectancy (1990, Females)	71.6
Life Expectancy (2017, Females)	79.1

Table 2 shows that Brazil has three clusters of major risks that drive their burden of death and disease: unhealthy diets, alcohol and tobacco. There are well documented synergies between alcohol and tobacco use best demonstrated in causing oesophageal cancer and IHD. It should be noted that while lung cancer did not appear in the top causes above, it is a major cause of death accounting for 38 000 deaths in

Top 10 Causes of Death (by rank)			
1	Ischemic heart disease		
2	Stroke		
3	Lower respiratory infections		
4	COPD		
5	Interpersonal Violence		
6	Diabetes		
7	Alzheimer`s Disease		
8	Road Injuries		
9	Chronic Kidney Disease		
10	Cirrhosis Liver		

2022 with IARC projecting this to increase to 71 000 by 2045 (IARC). Brazil already accounts for more to-bacco deaths than Argentina, Mexico, Columbia and Peru combined.

Table 3:

Smoking rates in Brazil (3)

Criteria	Year	Brazil
	2018 (overall)	13.4
Tobacco Smoking Rates (% adults)	2018 (male)	17.3
	2018 (female)	9.6
	2018 (overall)	22300
Number of Tobacco Smokers (thousands)	2018 (male)	14100
	2018 (female)	8300





CHAPTER 6

Key aspects of tobacco control legislation in selected countries

Table 4:

Key aspects of tobacco control legislation (3)

Status of MPOWER Measures	Brazil		
Monitoring	Recent, representative and periodic data for both adults or youth		
Smoking Bans	All public places completely smoke-free (or at least 90% of the population covered by complete subnational smoke-free legislation)		
Cessation Programmes	National quit line, and both NRT and some cessation services cost-covered		
Health Warnings	Large warnings with all appropriate characteristics		
Mass Media	National campaign conducted with one to four appropriate characteristics		
Advertising Bans	Ban on all forms of direct and indirect advertising (or at least 90% of the population covered by subnational legislation completely banning tobacco advertising, promotion and sponsorship)		
Current State of Taxation (2022 Indicator and Compliance)	30.2%		
Cigarettes less affordable since 2012	Cigarettes more affordable - per capita GDP needed to buy 2000 cigarettes of the most sold brand declined on average between 2012 and 2022.		





Table 4 shows the current state of progress using WHO MPOWER reports complemented by the latest legislative and tax policies focused on THR products. Brazil has steadily implemented most provisions of the FCTC, placing it at the highest level of achievement by WHO for taxes, warnings, advertising bans, and support for farmers to transition (WHO GlobaL TB 2023). However, the implementation of the benefits of excise taxes are eroded by the extensiveness of illicit trade. For example, Szklo estimated in 2023 that 38.6 percent of cigarettes that were smuggled were illicit and almost 10% were legal but no taxes were paid. The highest levels of illicit were recorded in states bordering Paraguay. (14)

Further, Brazil banned E-cigarettes sales in 2009 and shortly after banned heated tobacco products. Despite the ban there are an estimated 10-12 million vape users of whom between 2.2 and 3.5 million are regular users according to Direta's Alexandro Lucian. The illicit cigarette and vape levels indicate the weakness of the state to enforce laws combined with the space created by bans and high taxes to meet consumer demands.

Nicotine pouches and snus are legal. Data of prevalence is tough to obtain. The last official national survey of smokeless tobacco products was carried out 11 years ago!





CHAPTER 7

Estimated adult smoker lives saved under various scenarios

7.1 Scenarios and potential lives saved

Table 5:

Smoking-related deaths and trends under various scenarios in Brazil

Criteria	Year	Brazil
Current Tobacco Use Rates Prevalence Trends (% adults)	2000	12.8
	2025	11.3
	2045	5
	2060	5
Tobacco deaths	2019	191
(thousands)	2045 THR	127
	2045 + Quit	95
	2060 WHO	127
	2060 THR	76
	2060 + Treat LC	60
Lives Saved 2020-2060 – Max*		1364
Lives Saved 2020-2060 - THR Only **		935

Figures based on Dr. Derek Yach's personal communication of estimates based on trends across the fields of neuroscience, addiction and pharmacology.

SOURCE: Campaign for Tobacco Free Kids (CTFK) website

THR: Applying 80% exposure reduction translating to 70% harm reduction

QUIT: 25% Reduction (50% quitting success applied to 50% of the smoke population)

TREAT LC (LUNG CANCER): Treat and diagnose lung cancer with 10% decline (assumes poor access continues)

^{*:} Cumulative lives saved 2020-2060 applying THR + QUIT + Treat above WHO projected status status quo **: Cumulative lives saved applying only THR





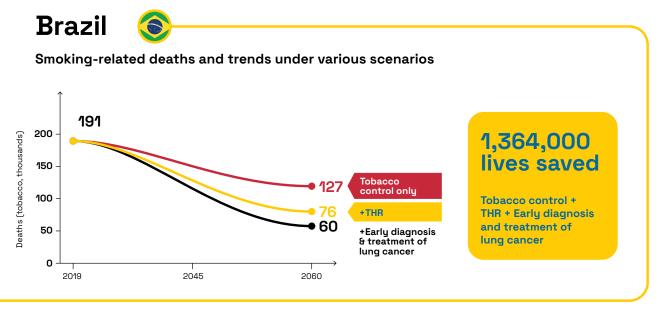


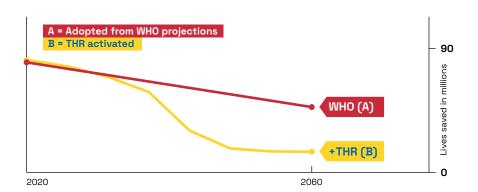
Figure 1: Schematic graphic showing the potential lives saved if Brazil were to embrace THR and early diagnosis and treatment of lung cancer.

Table 5 contains the output of the analysis and applies several assumptions 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 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 DALYS or the economic benefits of THR. That requires a separate, more detailed set of analyses ideally led by countries.

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.

Tobacco-related deaths will be reduced if THR policies implemented



Fewer tobaccorelated deaths, if THR policies implemented

Figure 2: Schematic graphic showing the cumulative deaths between 2020 and 2060, due to tobacco-related disease, in case of the status quo (WHO-directed tobacco control) and if tobacco harm reduction strategies (THR) were to be added





Figure 2 shows the WHO-projected tobacco deaths over time compared to projections where smokers adopt THR products. The area between the red and yellow lines represents the cumulative number of deaths expected if THR and related measures are deployed in addition to WHO strategies.

Given the lag between quitting and/or switching and a decrease in deaths, policymakers need to be kept motivated during years of little apparent progress. Within two decades, though, the benefits will become clear. If better access to treatment accompanies THR progress, the death rates can decline faster, even if incidence remains high.

7.2 Potential adult smoker lives saved through adoption of life saving technologies to 2060

Cumulative lives saved through adoption of life saving technologies to 2060

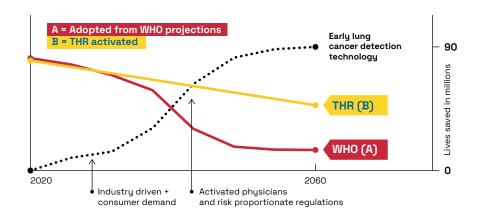


Figure 3: Schematic graphic showing the likely pace of THR technology uptake, and the lag between that and declines in tobacco-related deaths 2020-2060

Figure 3 highlights the crucial role of time in understanding how fast new THR technologies can reach tobacco users and have an impact, to help save the lives of adult smokers. We use a classic innovation diffusion curve, knowing it can change because of government actions and consumer demand. New technologies are usually first adopted by higher-income

urban consumers and, at some point, reach what Malcolm Gladwell calls a "tipping point" (35) when uptake accelerates. There will be a small group of usually less well-educated consumers for whom the innovations will not appeal. That is why projections stop at 90% of smokers.





CHAPTER 8

Actions are needed if we are to save millions of lives

8.1 End inaction now and save lives. WHO must act for health

The number of lives that would be saved through expanding access to THR is substantial and dwarfs almost any other single health intervention governments can implement. In just the four countries we studied previously, a total of 2.6 million lives could be saved through proven THR methods that are already working across the globe. Adding Brazil to this group pushes the lives of the 22 million adult smokers to be saved in just 5 countries close to 4 million over the next few decades.

There are currently about 22 million cigarette users in Brazil. Significant additional premature deaths will be prevented if a wider range of interventions are implemented (see Table 4). For every death prevented, there will also be considerable benefits in terms of decreased disease and suffering. And there will be considerable economic benefits to Brazil resulting from a reduction of direct health care costs and a boost to productivity.

A basic maxim on health policy is "if one can prevent, its ethically required to prevent". This study shows the scale of benefit if the technologies, already available, were made more widely available. It should be noted: over the next few decades, THR products will evolve to be even more accessible and effective at replacing cigarettes. They will become linked to wearables and digitally available, along with culturally appropriate behavioural support. This may well lead our estimates to be serious underestimates of what is possible.

Member States who took part in COP10 in Panama should review the COP Scorecard (13) we produced and use it as guidance to fully activate the potential of harm reduction, to complement the other aspects of tobacco control. Harm reduction is part of the very definition of tobacco control as stated in the FCTC.

WHO should be held accountable and their policy-making process transparent to avoid undermining sovereign nations and individual rights. There is a real danger that the poor scrutiny and accountability of the WHO FCTC might lead to the adoption of policies that will harm peoples' health. (26) The Scorecard (13) shows this is already the case.





8.2 Governments should lead efforts to save lives

The beauty of THR is that the considerable costs of innovation, marketing and distribution are carried by the private sector. Government should regulate nicotine products proportionate to the risk they pose to health and in ways that maximise benefits and make healthier choices as easy as possible. Taxes should be higher on deadly combustibles than on THR products. Marketing bans and warnings should discourage use of combustibles by adults and children but provide information about benefits to adult tobacco users. Access to combustibles and toxic smokeless products should be severely restricted, but access to THR products should be made widely available to adults.

For Brazil, there is an urgent need to reverse the sales ban on vapes and heated tobacco products. This will promote greater switching away from combustibles and reduce the growing size of an illicit market that will inevitably undermine national security even as it propagates unsafe products.

This approach contrasts with WHO recommendations and current practices in the five countries studied. This must change to focus on preventing tobacco-related disease and premature death.

In short - to save lives.

8.3 Physician leadership on THR is crucial: belief, practices and views require attention

Physicians led in the early years of tobacco control. They were the subjects of the earliest cohorts that showed that smoking kills. (27) They galvanised reports (28, 29) that led to the first government actions. They quit rapidly and in large numbers once they understood the evidence. They started cessation services for their patients, and they led the development of public health policies to end smoking.

It is time for an equivalent focus on THR. 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. It needs to start by correcting the massive extent of disinformation that has led to 77% of physicians in 16 countries incorrectly believing that nicotine causes lung cancer (23) and leads to physicians developing reports of equivalent impact to those of the Surgeon General and Royal College of Physicians. These need to be country specific and focused on national realities.

In addition to providing their patients with current evidence of the benefits of THR, they need to be more consistent about telling their patients who smoke, to quit or smoke less.

For decades, epidemiologists have documented strong dose-response relationships between smoking and major outcomes. This work was recently updated in a major review by IHME. (16) It shows fiveto-seven-fold differences in mortality rates between smokers who consume five or fewer cigarettes a day versus those who smoke 20-30 cigarettes a day. These relationships held for lung cancer, tuberculosis (TB), ischaemic heart disease (IHD) and chronic obstructive pulmonary disease (COPD). They strongly suggest that if smokers were encouraged to cut back on daily smoking, they would see a substantive decline in tobacco-related health outcomes. The size of the benefit of cutting back is related to how long people have smoked and at what levels but could be substantive at every age.

Earlier, we provided updated evidence of the benefits of cessation at every age and stressed the reality that THR offers the best form of achieving this.

These insights have implications for current debates about dual use. Any dual use is likely to include smoking fewer cigarettes – that alone will cut smokers' risk





8.4 The voice of THR could be decisive

There is much to be learned from breast cancer and HIV/AIDS. In both cases it was patients and advocates who rallied for better policies under the banner of "nothing about us, without us." Organised patient groups, vocal users of antiretrovirals and friends of people with disease have built movements that demanded seats at the table when policies affecting their lives are discussed. And they have achieved this.

While we have fledgling new nicotine user groups, they have yet to galvanise into a movement with impact. Their advocacy to highlight the tobacco-related deaths that can be prevented, according to this study, is a much-needed element. The good news is that Brazil has a strong Non-governmental Consumer Organization (Direta) that advocates for sensible regulation of vapes noting that while the 2009 law bans sales, it does not ban possession or use. (15) This

creates the conditions for massive illicit trade primarily from China. Such organizations face daunting odds in a country with Bloomberg Philanthropies and its grantees actively and aggressively opposing any progress in THR and using their access to the highest political offices to maintain the status quo.

The strength of consumer voices can also be seen in the response to the public consultation on vaping recently held by the Brazilian Health Regulatory Agency (ANVISA). This consultation received submissions from more than 14,000 individuals – with 58.8% opposing the prohibition on electronic devices and 57.7% sharing the belief that the prohibition has negative impacts on society. (20)

8.5 Industry must do more to provide access to THR in LMICs and to obtain medical licenses for THR products

We previously outlined the reality that most companies focus their sales, marketing and even research in high income countries and have yet to devote the needed attention to LMICS, where 80% of smokers live. That is slowly changing, but far more needs to be done.

Nicotine pouches and snus are one bright spot within the THR world of Brazil. Many major brands are available on the legal market and are seen as affordable, can be used discreetly, and are considered satisfying by people who switch from smoking. This could signal the first move towards displacement of combustibles, similar to the introduction of heated products into Japan a decade ago. One hopes that manufacturers will step up their efforts to ensure access across Brazil

while making sure that marketing and sales regulations are scrupulously adhered to.

With few exceptions, the tobacco industry has not developed THR products that meet medical licensing regulations (except Imperial and BAT). (30, 31) This is needed to provide physicians with medically approved products, that they can use in their clinical settings. In addition, the halo effect of this could have widespread implications for how physicians support all forms of THR outside of the clinical setting and give an assurance to smokers that such products are much less harmful and effective. It is also the only THR policy that traditional academic opponents and supporters of THR agree is needed.



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Dr. Yach is a former employee of the World Health Organization and of PepsiCo.

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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 Welcome Trust.



ERIKA SUZIGAN - BRAZIL

Erika Suzigan is a physical medicine and rehabilitation physician and academic coordinator of the medical course at Universidade do Oeste Paulista, Guarujá campus. She is a doctoral student at the same institution, in the field of Education; she has a master's degree in Health Sciences (2018) from the Faculty of Medical Sciences of Santa Casa de Misericórdia de São Paulo, where she also graduated in Rehabilitation Medicine (2010). She graduated in Medicine from the ABC Medical School in 2006. Since 2010, she has worked as a physiatrist and as a teaching assistant for residents in the rehabilitation services at Santa Casa de São Paulo, the Association for Assistance to Disabled Children (AACD) and SESI. In addition to outpatient care, she also has experience in in-hospital care, with professional experience at Hospital Alvorada and Hospital Geral de Pirajussara.



INGRID DRAGAN TARICANO - BRAZIL

Ingrid Dragan Taricano is a toxicologist, with a specialisation in xx. She holds a degree in Biological Sciences from UNISA - University of Santo Amaro, a master's degree in Pharmacology from the Paulista School of Medicine UNIFESP and a doctorate in Veterinary Medicine (Applied Toxicology) from the University of São Paulo. She has served as the director of the UNITOX laboratory, and also held the position of Director of the Faculty of Biomedicine at UNISA.



DR. DELON HUMAN - SOUTH AFRICA, FRANCE

Dr. Delon Human is a specialist family physician, global health advocate, published author, international speaker and health care 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.







DR. S. ABBAS RAZA - PAKISTAN

Dr. Raza is currently a Consultant Endocrinologist at Shaukat Khanum Hospital and Research Center in Pakistan and National Defence Hospital in Lahore, Pakistan, since 2004. He received his medical degree from Allama Iqbal Medical College, Lahore, and was Chief Medical Resident at Atlantic City Medical Center, NJ, USA. Fellowship in Diabetes, Endocrinology and Metabolism was completed at University Wisconsin, Madison, USA. Dr Raza is American Board Certified in Internal Medicine, and in Endocrinology, Diabetes and Metabolism.

He has presented extensively on diabetes and endocrinology throughout his career and has received numerous awards in recognition of his contributions to this field. He has been Awarded Tamghae-Imtiaz by President of Pakistan for services in field of Medicine.

Dr Raza is an Executive Member (since 2004) and President of International Society of Endocrinology (2022- 2024), Past-President of the Pakistan Endocrine Society (PES), South Asian Federation of Endocrine Societies (SAFES) and Pakistan Chapter of American Association of Clinical Endocrinologist. He was also previously on the Board of Directors for the American Association of Clinical Endocrinologists (AACE) (2003–2004).



DR. KGOSI LETLAPE - SOUTH AFRICA

Dr. Kgosi Letlape is an ophthalmologist from South Africa, and is currently a founding member of the Africa Harm Reduction Alliance (AHRA), a former president of the Health Professions Council and chairman of the Medical and Dental Board of South Africa. He is the current president of the Africa Medical Association and president of the Association of Medical Councils of Africa. He is also past chairman of the board of the South African Medical Association (SAMA) and past president of the World Medical Association (WMA), the global representative body for physicians. He was admitted as a fellow of the College of Surgeons of South Africa in April 1988 and as a fellow of the Royal College of Surgeons of Edinburgh for ophthalmology in May 1988. He has the distinction of being the first black African to qualify as an ophthalmologist in Southfield, South Africa, and the first to become president of the WMA.

Internationally, Dr. Letlape has been closely involved in policy on a range of issues – from the ethics of clinical research to health care systems and the FCTC. During the last decade, he has focused on harm reduction policy and science. He brings to the table superior, world-class skills of leadership, advocacy and policy insight.



PROF. MIHAELA RĂESCU - ROMANIA

Prof. Dr. Răescu (Dentist) teaches Oral and Dental Prevention at the Faculty of Dental Medicine of the "Titu Maiorescu" University in Bucharest, Romania since 2003 and has been a tenured professor since 2015, in addition to being an active practitioner and a Specialty Doctor, Dr. Răescu has authored and co-authored numerous studies and publications and has been a guest speaker at various professional conferences.







DR. ANDERS MILTON - SWEDEN

Dr. 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 and current chair of the Snus Commission. He is the 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).



PROF. KARL-OLOV FAGERSTRÖM - SWEDEN

Prof. Karl Fagerström is a psychologist and founding member of the Society for Research on Nicotine and Tobacco (SRNT). He was awarded the World Health Organization medal in 1999 for his outstanding work in tobacco control. In 2013 he was the recipient of the Award on Clinical Science from the Society for Research on Tobacco and Nicotine. He has been part of the early development of the Nicotine Replacement products and developed the first non-tobacco nicotine pouch.



DR. DIEGO VERRASTRO - ARGENTINA

Dr. Diego Verrastro is a general surgeon, specialising in emergency medicine, abdominal miniinvasive 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.



PROF. HEINO STÖVER - GERMANY

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.







DR. ANOOP MISRA - INDIA

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.



DR. HIROYA KUMAMARU - JAPAN

Cardiovascular surgeon. Hiroya Kumamaru is vice director of AOI International Hospital in Kawasaki, Japan, a position he has held since April 2013. A graduate from the School of Medicine at Keio University, Kumamaru studied cardiovascular surgery in Europe and the United States. His professional experience includes time spent as director of the K.I. Akihabara Clinic (July2008 to March 2013), chief surgeon of the department of cardiovascular surgery at Kawasaki Municipal Hospital, Kanagawa (July 2005 to March 2008) and senior cardiovascular medical director and group leader of clinical scientific affairs at Pfizer Japan (April 1996 to June 2005).





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