

REPORT

INTEGRATING HARM REDUCTION INTO TOBACCO CONTROL

How many lives could be saved by accelerating tobacco control policies in Kazakhstan, Pakistan, South Africa, and Bangladesh?

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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.

This report addresses the pressing issue of tobacco control policies in four Low Middle-Income Countries (LMICs), Kazakhstan, Pakistan, South Africa, and Bangladesh where a total of 350 000 people die prematurely from tobacco use each year.

In these four countries there is a significant gender gap in smoking rates and related deaths, contributing to differences in life expectancy. In two of these countries, Pakistan and Bangladesh, toxic smokeless tobacco product use is common. In addition, tobacco-related causes, including heart disease, chronic obstructive pulmonary disease (COPD), stroke, lung cancer and tuberculosis (TB), are among the leading causes of death in all these nations.

The report aims to provide policymakers and public health experts with estimates of the potential benefit of tobacco harm reduction (THR), improved cessation, and better access to lung cancer diagnostics and treatment on reducing premature deaths.

The study considers the crucial role of time in addressing tobacco-related diseases, emphasizing that the benefits of cessation or harm reduction take decades to fully manifest.

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 these countries through the widespread adoption of THR and related measures. For instance, Kazakhstan could prevent 165 000 premature deaths in the next four decades, while South Africa, Bangladesh and Pakistan could save 320 000, 920 000, and 1 200 000 lives, respectively.

This report demands several actions. Member States at COP10 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. 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) for 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 low- and middle-income countries (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 WHO FCTC does not mention the role of innovation, technology improvements, and the need to adapt policies as these become available. Yet over the last two decades 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-ciqarettes, 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.

COUNTRY-SPECIFIC STUDIES OF LIVES SAVED ARE NEEDED

This study focuses on Kazakhstan, Pakistan, South Africa, and Bangladesh where a total of 350 000 people die prematurely every year of combustible tobacco and toxic smokeless tobacco products. The latter being most important in Pakistan and Bangladesh. These are all LMICs and have many other competing priorities for health. They also are characterized by having weak enforcement capacity of government regulations and have severe understaffing of the health sector.

In all four countries, smoking rates are high among men and there is a wide gap between smoking rates and related deaths among men versus women (Table 1). This partly explains the wide gap in life expectancy favouring women in these countries. For example, life expectancy among women in Kazakhstan is nearly a decade longer than men (76.4 versus 67.5), and 7 years longer among women versus men in South Africa (69.7 versus 62.8). (7, 8) Further, tobacco-related causes of death rank within the top 10 causes in all these countries. They include ischemic heart disease (IHD), COPD, stroke, lung cancer and TB.

Between them, these countries offer a window into LMICs struggling to end smoking. Pakistan and Bangladesh represent countries in Southeast Asia that are similar in terms of their tobacco use to India. The results from these countries thus should have implications for the over 1 billion people living there. The South African experience has implications across many other African and low middle income countries. Tobacco use in Kazakhstan follows a similar pattern to many other countries that were part of the Soviet Union and share common distribution and supply chains that could be leveraged for faster progress.

CALCULATING THE "SIZE OF THE PRICE"

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 since tobacco-related diseases are chronic conditions that take decades before the full benefits of cessation or harm reduction are visible in national data. This is a critical point to appreciate.

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 three to four decades.



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 (see Table 1 below).

2.1 Prospective modelling – simulation modelling to calculate potential tobacco-related deaths averted and life years gained

Table 1:

A summary of key studies that demonstrate prospective simulation modelling to calculate potential tobacco-related deaths averted and life – years gained.

| Author and study name | Country | Finding |
|--|---|---|
| Levy et al Public health implications of vaping in the USA: The smoking and vaping simulation model (11) | USA (2013-2060) Canada (2012-2052) | The net outcome of smokers switching to nicotine vaping products will translate into: 1.8 million fewer smoking-related premature deaths 38.9 million life years gained 130 000 deaths avoided 3.5 million life years saved |

| | Germany (2013-2060) England (2012-2052) | 300 000 deaths avoided 4.7 million life years saved 200 000 deaths avoided 5 million life years avoided |
|--|--|--|
| Warner and Mendez E-cigarettes: Comparing the Possible Risks of Increasing Smoking Initiation with the Potential Benefits of Increasing Smoking Cessation (12) | USA | The US population would gain almost 3.3 million life years by 2070 if smokers switched to e-cigarettes |
| Ramström and Wikmans Mortality attributable to tobacco among men in Sweden and other Eu- ropean countries: an analysis of data in a WHO report (13) | European Union (EU) | In men over the age of 30, in the EU, 355 000 lives per year could have been saved if the other EU countries had matched Sweden's tobacco-related mortality rate. |
| Lee et al Estimating the reduction in US mortality if cigarettes were largely replaced by e-cigarettes (14) | USA | Over a 50-year period from 1990, the estimated reduction in deaths would be 2.52 million, 11.4% of the total number of deaths from the diseases considered. The reduction in years of lives lost (YLL) would be 26.23 million. |



2.2 Retrospective modelling

A comparison of tobacco-attributed mortality between 2000-2019 in Sweden versus the EU, using data from the IHME's Global Burden of Disease Study, (15) showed that potentially 2.9 million premature deaths could have been averted.

Table 2:

A comparison of tobacco-attributed mortality between 2000-2019 in Sweden versus the EU using data from the IHME's Global Burden of Disease Study. (15) The column 'EU (if rate like Sweden)' is a hypothetical figure calculated by the following equation: (EU actual number of deaths / EU death rate) multiplied by Sweden's death rate. Looking at 'all causes', if the EU had the same smoking-attributable death rate as Sweden during these 20 years, potentially 2.9 million deaths could have been averted.

| Smoking-attributable deaths: Sweden vs EU (2000-2019) | | | | | | |
|---|--|---------|-----------------------|-----------------------------|--------------------------------------|--|
| Cause of death | Smoking-attrib rate per ' (2000- | 100 000 | 00 000 deaths, number | | Deaths that could have been averted, | |
| | Sweden | EU | EU (actual) | EU (if rate like Sweden) | number | |
| Non-communica- ble disease (NCD) | 139.9 | 167.6 | 16 870 287 | 14 082 789 | 2 787 499 | |
| All cancers | 56.0 | 79.6 | 8 020 071 | 5 637 051 | 2 383 020 | |
| Respiratory tract cancers | 28.4 | 44.0 | 4 434 576 | 2 858 811 | 1 575 765 | |
| COPD | 18.9 | 23.2 | 2 336 499 | 1906 782 | 429 717 | |
| Cardiovascular disease | 52.7 | 55.2 | 5 541 923 | 5 294 089 | 247 834 | |
| Lower respiratory tract infections | 5.0 | 5.9 | 595 510 | 503 637 | 91 873 | |
| All causes | 145.8 | 174.5 | 17 562 390 | 14 672 386 | 2 890 004 | |

The above modelling studies all have several common features:

- They model the impact of e-cigarettes, snus and heated tobacco products on future health, comparing results to the use of combustible cigarettes. (11, 12) They do not model the impact of combinations of product types, nor do they consider the overall impact of the rapidly emerging new innovative products and categories.
- They model effects over several decades (11, 12) but have tended to report on changes within the next decade. This misses the largest category of lives to be saved – those that occur beyond 2040.
- They do not consider improvements in effectiveness and access to THR education and products,

- cessation or changes in survival and quality of life expected for major tobacco related diseases (like lung, oral cancer and COPD).
- They do not consider dose-response relationships and how these have implications for assessing the impact of dual use between THR products and combustibles. (16)

Despite these shortcomings, the published studies that use models indicate substantial health gains are likely, if smokers switched to e-cigarettes, oral nicotine pouches, snus, or heated tobacco products. Importantly, only the Swedish studies provide actual data on health gains without relying on future projections. (13)



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.

This preliminary study shines a light on the potential for THR to have major beneficial impacts on premature deaths and, implicitly, the quality of life in four low- or middle-income countries (LMICs). We hope that the power of the data will motivate policymakers to fully

embrace THR and related elements, specifically within the context of all LMICs, where there is generally a lack of awareness of the adverse effects of smoking. In addition, poor detection and management of lung cancer and other tobacco-related co-morbidities.

DEMONSTRATING PUBLIC HEALTH BENEFITS IN LMICS

To determine likely declines in premature deaths from tobacco use in four countries: Kazakhstan, Pakistan, Bangladesh and South Africa between 2030 and 2060, if there were increased awareness and use of THR, better diagnosis, greater access to more effective cessation services and treatment of lung cancer.

Methods

The approaches used by seasoned "modellers" were reviewed and simplified to their essential elements. (See Table 1.)

4.1 Survey

International experts and doctors from the four countries were consulted to get quantitative answers to the questions below. Their responses were used to inform the estimates used in determining "lives saved".

Q1. How effective do you believe nicotine replacement therapies (NRTs) are in smoking cessation at one year and in reducing the burden of disease it causes?

The median result was that experts believed NRTs are less than 10% effective at one year. This is in line with most reviews. (20) Among those who quit, they believed that NRTs were moderately effective in reducing tobacco-related health outcomes.

Q2. How much do you believe that exposures to toxic aspects of cigarettes and smokeless products are reduced when users shift to harm reduction products?

The median result was 80% plus. Published reviews put this figure as high as 98% for nicotine pouches and e-cigarettes. (21)

Q3. How long do you believe it takes for smokers who have quit to lower their risks of lung cancer, COPD, IHD and TB?

The median overall view was that it would take five years for the disease rates to reduce. This is at odds with large cohort studies that have examined this and suggest that it takes 25-30 years for lung cancer, 30 years for COPD, and 10 years for IHD and TB rates to decline. In smokers who quit before 35-40 years of age, however, risks rapidly reduce to be equivalent to those of never smokers within five years. (22)

Q4. How much (in percentage) do you believe smokers reduce their risks of lung cancer, COPD, IHD and TB over

a 10-, 20- and 30-year period after quitting or switching to THR?

Median results suggest that a 70% reduction in harm for all outcomes within 20 years is expected with higher reductions possible over the 30-year horizon. The modelling studies are in line with these results, with some using 80% as their estimate. They are probably too conservative and as biomarkers of outcome and harm are increasingly used, we should be able to refine these. (22)

Q5. In your country, what is the current survival rate of people who contract lung cancer by stage? At what stage are most patients diagnosed?

The median results suggested that 20% of lung cancer patients globally survive five years post diagnosis and that diagnosis usually occurs at stages 3 or 4.

Q6. How fast do you feel it is possible to achieve 60%, 70%, 80% and 90% uptake of THR if they are approved by government? Base your answers on real world experience with access to antiretroviral drugs (ARVs) and other widely used treatments.

Experts believe that 65% of their population of smokers could have access to THR within a decade if the government were supportive.

Q7. Do you believe that nicotine causes lung cancer? (a qualitative question)

This well-informed group mainly believed that nicotine does not cause cancer. This contrasts with a large global survey of 16 000 physicians. About 70% of the respondents across 12 countries stated that they believed that nicotine causes lung cancer (which it does not). (23)



4.2 Assumptions

After integrating the expert views with published research, the following assumptions are made in calculating lives saved in the four countries.

- At present, NRTs are 10% effective at one year.
- The spectrum of THR products reduce toxic exposures by 80% and reduce tobacco-related causes of premature death by 70%.
- 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 Kazakhstan, by 50% in Pakistan, 25% in Bangladesh, and not at all in South Africa. We suggest this could accelerate to 50% from 2030 in all countries.(3)

4.3 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-re-

lated diseases. Trends that include THR and better access and use of diagnostics and treatments (focused mainly 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.



Key data in selected countries

Table 3:

Country demographics and epidemiology (7, 8, 25, 26)

| Criteria | South Africa | Bangladesh | Pakistan | Kazakhstan |
|------------------------------------|---------------------------|---------------------------|----------------------------|---------------------------|
| Population (in million) | 55.6 | 159.3 | 224.1 | 18.4 |
| Life Expectancy (2000, Males) | 52.9 | 64 | 62.2 | 60.3 |
| Life Expectancy (2017, Males) | 58.3 | 71.8 | 66.3 | 67.5 |
| Life Expectancy (2000, Females) | 58.3 | 67.6 | 61.6 | 71.1 |
| Life Expectancy (2017, Females) | 69.7 | 74.6 | 67.4 | 76.4 |
| Top 10 Causes of Death | (by rank) | | | |
| 1 | HIV/AIDS | Stroke | Neonatal disorders | Ischemic heart disease |
| 2 | Ischemic heart disease | Ischemic heart disease | Ischemic heart disease | Stroke |
| 3 | Stroke | COPD | Stroke | COPD |
| 4 | Lower respiratory infect | Neonatal disorders | Diarrheal diseases | Cirrhosis liver |
| 5 | Diabetes | Lower respiratory infect | Lower respiratory infect | Cardiomyopathy |
| 6 | Tuberculosis | Diabetes | Tuberculosis | Self-harm |
| 7 | Road Injuries | Diarrheal diseases | COPD | Lower respiratory infect |
| 8 | Interpersonal Violence | Tuberculosis | Diabetes | Lung cancer |
| 9 | Neonatal disorders | Cirrhosis liver | Chronic kidney diseases | Road injuries |
| 10 | Diarrheal diseases | Other malignant neoplasms | Cirrhosis liver | Diabetes |



Table 4:

Smoking rates and trends in the four countries* (3)

| Criteria | Year | South Africa | Bangladesh | Pakistan | Kazakhstan |
|---------------------------------------|----------------|--------------|------------|----------|------------|
| | 2020 (overall) | 20.2 | 18.6 | 13.1 | 20.9 |
| Tobacco Smoking Rates (% adults) | 2020 (male) | 34.6 | 36.4 | 22.7 | 37.7 |
| | 2020 (female) | 6.5 | 0.5 | 3.1 | 5.8 |
| | 2020 (overall) | 8,537 | 22,409 | 18,879 | 2,777 |
| Number of Tobacco Smokers (thousands) | 2020 (male) | 7,12 | 22,096 | 16,734 | 2,372 |
| , | 2020 (female) | 1,418 | 313 | 2,175 | 405 |

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



Key aspects of tobacco control legislation in selected countries

Table 5 shows the current state of progress using WHO MPOWER reports complemented by the latest legislative and tax policies focused on THR products. Progress on banning tobacco advertising and improving access to smoke-free environments in these countries contrasts with less progress in increasing taxes on combustibles and improving access to cessation services through primary healthcare facilities. Regulatory progress on THR remains bleak, which hampers real progress.

Table 5:

Key aspects of tobacco control legislation (3)

| Status of MPOWER Measures | South Africa | Bangladesh | Pakistan | Kazakhstan |
|---------------------------------|--|---|--|--|
| Monitoring | Recent and representative | e data for either adults or yo | Recent, representative and periodic data for both adults and youth | |
| Smoking Bans | Complete absence of ban, or up to two public places completely smoke-free Complete absence of Three to five public places completely smoke-free | | All public places completely smoke-free (or at least 90% of the population covered by complete subnational smoke-free legislation) | Six to seven public places completely smoke-free (moderate compliance) |
| Cessation Programmes | NRT and/or some cessation services (at least one of which is cost-covered) | NRT and/or some cessation services (neither cost-covered) | NRT and/or some cessation services (at least one of which is cost-covered) | |



| Health Warnings | No warnings or small warnings | Large warnings with all app | Large warnings with all appropriate characteristics | | |
|---|---|---|---|--|--|
| Mass Media | National campaign conducted with at least seven appropriate characteristics including airing on television and/ or radio | National campaign conducted with five to six appropriate characteristics | National campaign conducted between July 2020 and June 2022 with a duration of at least three weeks | National campaign conducted with five to six appropriate characteristics | |
| Advertising Bans | Ban on national television, indirect advertising (comp | , radio and print media as well as on some but not all other forms of direct and/or plete compliance) | | | |
| Current State of Taxation (2022 Indicator and Compliance) | 60.1% | 58.4% | 51.8% | 50.4% | |
| Cigarettes less affordable since 2012 | igarettes less affordable No trend change in affordability of cigarettes between 2012 Cigarettes less affordable – per capita GDP needed to buy 2000 cigarettes of the most | | No trend change in affordability of cigarettes between 2012 and 2022. | Cigarettes less affordable – per capita GDP needed to buy 2000 cigarettes of the most sold brand increased on average between 2012 and 2022. | |

Estimated adult smoker lives saved under various scenarios

7.1 Scenarios and potential lives saved

Table 6:

Smoking-related deaths and trends under various scenarios

| Criteria | Year | South Africa | Bangladesh | Pakistan | Kazakhstan |
|------------------------------------|-----------------|--------------|------------|----------|------------|
| Current Tobacco Use Rates | 2000 | 22.6 | 50.7 | 34.3 | 25.1 |
| Prevalence Trends | 2025 | 19.7 | 30.9 | 16.7 | 20.2 |
| (% adults) | 2045 | 10 | 15 | 8 | 10 |
| | 2060 | 5 | 5 | 5 | 5 |
| Tobacco deaths | 2020 | 40 | 126 | 163 | 22 |
| (thousands) | 2045 + THR | 26 | 82 | 114 | 14 |
| | 2045 + Quit | 20 | 62 | 76 | 11.2 |
| | 2060 SQ | 26 | 82 | 106 | 15 |
| | 2060 + THR | 16 | 53 | 66 | 9 |
| | 2060 + Quit | 12 | 40 | 50 | 7 |
| | 2060 + Treat LC | 10 | 36 | 45 | 6.5 |
| Lives Saved 2020-2060 - THR Only * | | 200 000 | 580 000 | 800 000 | 120 000 |
| Lives Saved 2020-2060 – Max ** | | 320 000 | 920 000 | 1200 000 | 165 000 |

SOURCE: Campaign for Tobacco Free Kids (CTFK)

THR: Applying 80% reduced exposure, translating to 70% harm reduction (Through the adoption of tobacco harm reduction (THR) strategies including risk-proportionate regulation and access to acceptable reduced risk nicotine products)

QUIT: 25% Reduction (50% quitting success applied to 50% of the smoke population)—through accelerated smoking cessation programs **SQ:** Traditional tobacco control

TREAT LUNG CANCER: Early diagnosis and treatment of lung cancer only, which could lead to 10% decline of tobacco-related deaths

*: Cumulative lives saved applying only THR

^{*:} Cumulative lives saved applying tobacco control + THR + QUIT + Early diagnosis and treatment of lung cancer



Table 6 contains the output of the consultation 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 rollout of MPOWER. For all countries, 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 projections 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

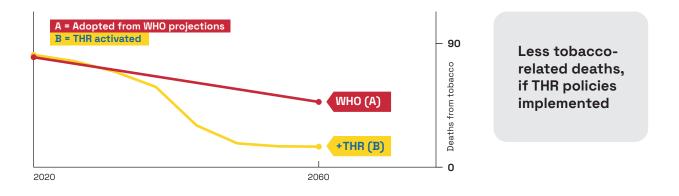


Figure 1: Schematic graphic showing the cumulative deaths between 2020 and 2060, due to tobacco-related disease, in case of the status quo (WHO-directed tobacco control) and if tobacco harm reduction strategies (THR) were to be added

Figure 1 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

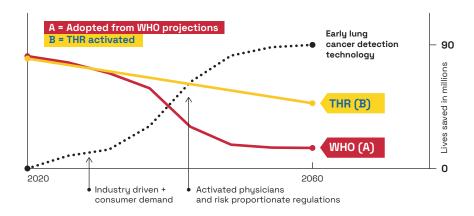


Figure 2: Schematic graphic showing the likely pace of THR technology uptake, and the lag between that and declines in tobacco-related deaths 2020-2060

Figure 2 highlights the crucial role of time in understanding how fast new THR technologies can reach tobacco users and have an impact, to help save 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" (27) 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.



7.3 Potential adult smoker lives saved in selected countries, under various scenarios

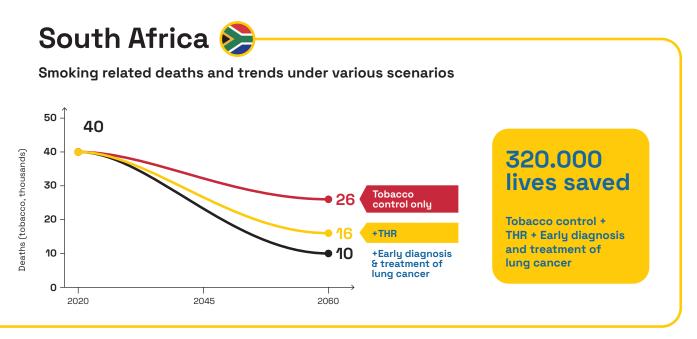


Figure 3: South Africa - potencial lifes saved by THR

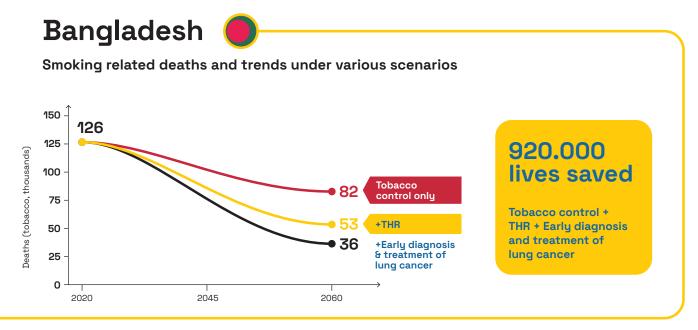


Figure 4: Bangladesh - potencial lifes saved by THR

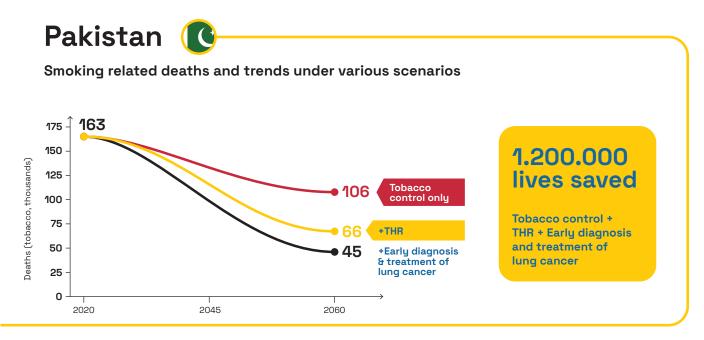


Figure 5: Pakistan potencial lifes saved by THR

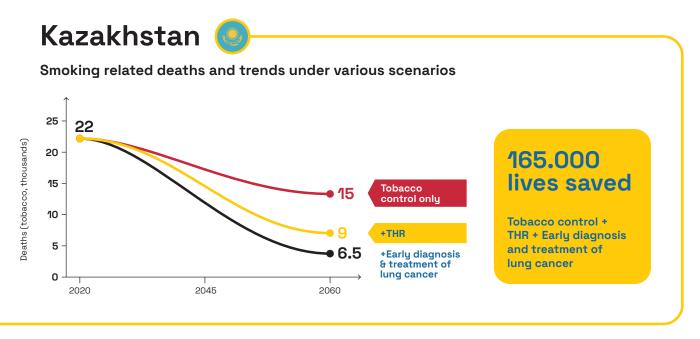


Figure 6: Kazakhstan potencial lifes saved by THR



Where are we seeing rapid declines in cigarette use today?

There are countries where progress is well underway. Apart from the UK, this is being driven primarily by industry innovation and consumer demand, with governments' active engagement in setting regulations to accelerate change being minimal. The declines in cigarette use are strongly linked to increased use of e-cigarettes (in the UK and USA), heated tobacco products (in Japan), nicotine pouches in Pakistan, and snus/nicotine pouches in Sweden.

For Bangladesh and Pakistan, both countries are beset by very high levels of oral cancer caused using toxic smokeless tobacco and areca nut products. Oral nicotine pouches offer a way to eliminate oral cancer over time. For these countries, early diagnosis of the precursors to oral cancer combined with large programs to encourage switching should lead to rapid declines in highly preventable oral cancers. It should be noted that this would primarily benefit low income and rural users in these countries, who are generally neglected by health services.

Recent reports (28) provide evidence about which THR category is growing fastest by country. A recent report shows that progress remains mainly focused on high income countries with very slow progress in most of the largest LMICs with millions of tobacco users. (3, 28) This lack of availability of THR products in LMICs is occurring even in countries where these products have not been banned. (28)

8.1 Japan

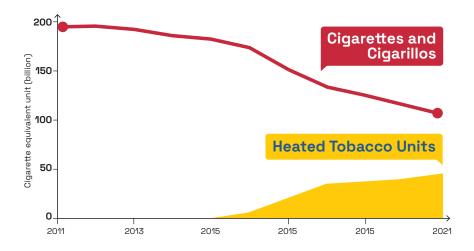


Figure 7: In-market sales volume of cigarettes and heated tobacco product units in Japan (29)



8.2 Sweden (snus and pouches)

Smoking incidence & use of snus & nicotine pouches (%)

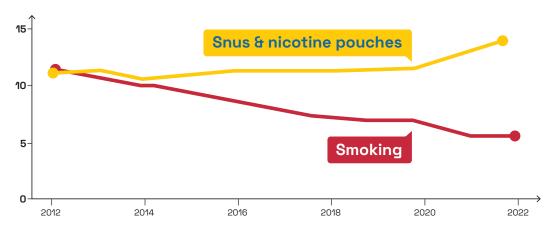


Figure 8: Source. Figures from Statistics Sweden

Figures compiled from combination of Fagerström and Public Health Agency of Sweden. (30, 31)

8.3 United Kingdom

Cigarette Smoking vs. Vaping in the UK

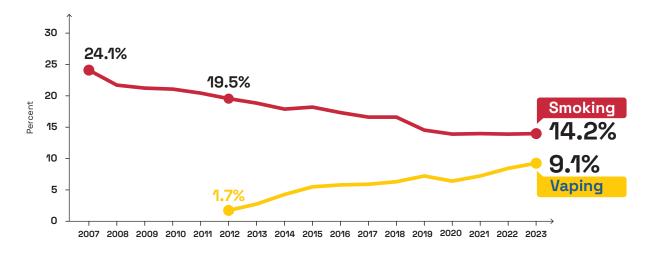


Figure 9: Decline of smoking prevalence and increase in vaping prevalence in the UK

Graph that shows percentage of people who vape in Britain vs percentage of smokers up to 2022.

Figure based on a combination of sources. (32, 33, 34, 35)





8.4 United States

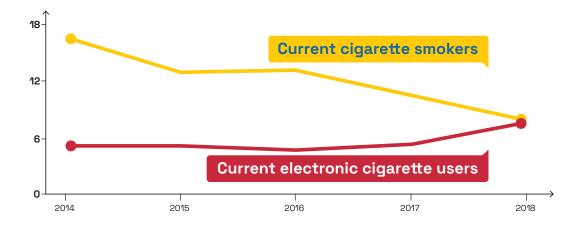


Figure 10: Percentage of adults aged 18-24 years who currently smoke cigarettes* or who currently use electronic cigarettes, t by year — National Health Interview Survey, United States, 2014-2018§ (36)

8.5 Pakistan / India / Bangladesh

In Pakistan, 23.9 million individuals (19.1%) smoke regularly, according to statistics. Around 6.2% of the population uses vaping or e-cigarettes, while 15.9 million (12.4%) use smokeless tobacco (SLT) in the form of Naswar. (37)

Table 7:

The use of tobacco-based products in Pakistan, India and Bangladesh (37)

| Country | Tobacco | Smokeless tobacco | Vaping/E-cigarettes | Total |
|------------|----------------------|-----------------------|---------------------|-----------------------|
| Pakistan | 23.9 million (19.1%) | 15.6 million (12.4%) | 6.2% | 9.6 million (7.7%) |
| India | 99.5 million (10.7%) | 199.4 million (21.4%) | 268 000 0.02% | 266.8 million (28.6%) |
| Bangladesh | 19.2 million (18.2%) | 22 million (20.6%) | 0.2% | 37.8 million (35.3%) |

Actions are needed if we are to save millions of lives

9.1 End inaction now and saves lives. WHO must act for health

The number of lives that would be saved through expanding access to THR is substantial and probably dwarfs almost any other single health intervention governments can implement. In just the four countries we studied, a total of 2.6 million lives could be saved through proven THR methods that are already working across the globe.

Significant additional premature deaths will be prevented if a wider range of interventions are implemented (see Table 6). For every death prevented, there will also be considerable benefits in terms of decreased disease and suffering.

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 taking part in COP10 in Panama should act to fully activate the potential of harm reduction, to complement the other aspects of tobacco control. After all, harm reduction is part of the very definition of tobacco control as stated in the FCTC. This will require reversing plans to dismiss, ban, overregulate and demonise THR, as outlined in WHO's own documents prepared for COP10. (38)

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. (39)



9.2 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 substantially 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.

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

In short - to save lives.

9.3 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. (40) They galvanised reports (41, 42) 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 lead 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 for smoking and major

outcomes. This work was recently updated in a major review by IHME. (16) It shows five-to-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.

Further, Jha et al showed that quitting brings life expectancy gains all the way through to those in their 60s. (44) In other words, it's never too late to quit if improved health is the goal. We do not have equivalent data for those switching to THR products, but emerging data on the use of biomarkers of outcome suggest that several cancers, heart, and lung diseases will decrease as smokers switch. (45)

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 of premature death. This point needs to be amplified.

9.4 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 effecting 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.

9.5 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.

With few exceptions, the tobacco industry has not developed THR products that meet medical licensing regulations (except Imperial and BAT). (46, 47) This is needed for two reasons. Provide physicians with

medically-approved products that they can use in their clinical settings. 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. (58)



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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. (49)



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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.



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Riccardo Polosa, full professor of internal medicine at the University of Catania and founder of the Center of Excellence for the Acceleration of Harm Reduction

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The focus of his academic research has been historically centered upon the investigation of mechanisms of inflammation, biomarkers of disease activity, and novel drug target discovery in the area of respiratory medicine (asthma, COPD, rhinitis) and clinical immunology (allergic and autoimmune diseases). This has culminated with 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 the area of tobacco-related diseases, smoking prevention and cessation, tobacco harm reduction and e-vapor products. More specifically, he has been involved in the behavioral, clinical, physiological and toxicological evaluation of e-cigarettes for over 10 years. Pl 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 designed and conducted dozens of research studies, working with smoking cessation specialists, clinical psychologists, experienced vapers, epidemiologists, biostatisticians, chemists, toxicologists and biologists from all over the world.

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). (50)



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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 Lat-n - 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.



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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.



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