GSTHR
2020

BURNING
ISSUES

BURNING ISSUES

GLOBAL STATE OF TOBACCO
HARM REDUCTION

2020

Contents

Acknowledgements

Executive Summary

Tobacco harm reduction

The central theme of this report, enshrined in many international treaties, is the universal right to health, including for those who for whatever reason continue to engage in risky behaviours. Harm reduction refers to a range of pragmatic policies, regulations and actions which either reduce health risks by providing safer forms of products or substances, or encourage less risky behaviours. Harm reduction does not focus primarily on the eradication of products or behaviours.

The humane response, instead, is to reduce the risks, thereby enabling people to survive and live better – in this case through access to safer nicotine products (SNP) aimed at encouraging people to switch away from cigarettes, one of the most dangerous ways of consuming nicotine.

The global smoking problem continues unabated, but there are glimmers of hope in some countries

Image: Obby RH on Unsplash

The World Health Organization (WHO) has not revised downwards its estimate that one billion lives could be lost to smoking-related disease by the end of the century. This is equivalent to the combined populations of Indonesia, Brazil, Nigeria, Bangladesh and the Philippines dying from COVID-19.

And while daily adult smoking levels have fallen across the world, the rates of decline have slowed in some countries. In others, the numbers of smokers have increased, often due to population growth. The highest reported levels of smoking occur mainly but not exclusively in low and middle-income countries (LMIC) which consequently shoulder the heaviest burden of disease and mortality. There are 22 countries where 30 per cent or more of the overall adult population are current smokers. These countries include Pacific islands such as Kiribati and the Solomon Islands, several European countries including Serbia, Greece, Bulgaria, Latvia and Cyprus, Lebanon in the Middle East, and Chile in South America.

The estimated total number of smokers globally – at 1.1 billion – is static, the same number as in 2000 and predicted to be the same in 2025, disproportionally affecting poor and marginalised groups, especially in LMIC.

The WHO continues to express concern that the unabated levels of smoking will undermine attainment of the Sustainable Development Goals and ensure that the 2030 targets to reduce levels of non-communicable disease will be missed. Clearly then, traditional tobacco control interventions elaborated in the WHO Framework Convention on Tobacco Control (FCTC) are not enough. Tobacco harm reduction (THR) policies therefore should be regarded as complementary rather than inimical to reducing the global death and disease from smoking. The glimmer of hope is that some countries have taken a more inclusive approach to THR as part of the overall strategy towards a smoke-free world.

New product development...

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Product innovation continues to offer a wide choice to adult consumers looking to avoid smoking. The origins of vaping lay outside the orbit of tobacco multinationals and the creative disruption this caused was underlined by the success of JUUL, which, since 2018, rapidly overtook its rivals. Some of JUUL's early marketing to the young adult end of the smoking market clearly caused controversy, but the product delivered a nicotine experience sought by many in the wider market of adult consumers.

Vaping devices, already discreet and easy to use, are becoming technologically more sophisticated, making the term 'e-cigarette' increasingly redundant. More companies are involved in developing heated tobacco products (HTP), while new non-tobacco nicotine products are also coming onto the market.

...but the global number of SNP users remains small

Despite a more globally hostile environment for THR, our exclusive survey of global prevalence of SNP estimates that the overall figure stands at approximately 98m, of whom 68m are vapers. While from a public health perspective this is good news, it still means that after more than a decade of product availability, there are only nine users of SNP for every 100 smokers.

SMOKERS **1.1B**

68M VAPERS
20M HTP USERS
10M US SMOKELESS AND SNUS USERS
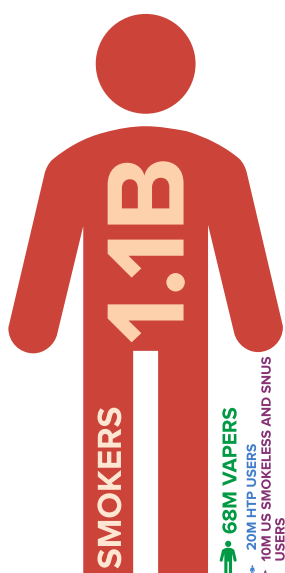
What is happening in different countries?

The highest number of vapers live in the United States, China, the Russian Federation, United Kingdom, France, Japan, Germany and Mexico. Japan has the highest number of HTP users while Sweden and the US have the highest number of snus consumers.

Use of SNP is holding up in countries such as the UK, Norway, Sweden, Iceland and Japan, although in the latter country, sales of HTP have slackened, possibly due to the number of early/younger adopters reaching saturation point.

The evidence confirms that safer nicotine products are just that – safer than smoking

There is no such thing as absolute safety, but the newer SNP have been in wide circulation for more than a decade, with accumulated evidence that they are much less risky than combustibles. Certainly since 2018, no robust evidence has emerged to throw doubt on the widely quoted conclusion of Public Health England that vaping is at least 95 per cent less risky than smoking and that emissions pose a negligible hazard to bystanders. Similarly, the relative safety record of Swedish-style snus and US smokeless products is unchanged from 2018. Moreover, there is growing evidence that use of SNP is more effective for smoking cessation than nicotine replacement therapy (NRT). This means over-interpretation of the 'precautionary principle' (the exercise of caution in the face of potentially harmful innovation) relating to health advice and regulation concerning SNP is no longer tenable.

Other concerns have been raised about the use of SNP. Misleading data from the US promoted the idea that JUUL was responsible for an epidemic of vaping among young people through the marketing of 'child-friendly' flavours, whereas more sober evaluations demonstrated that 'use' was very broadly defined covering experimentation and much rarer daily use. Lung injury and deaths in the USA were quickly determined by consumers and local health authorities (as opposed to US federal agencies) to be caused by the vaping of illicit tetrahydrocannabinol (THC) liquid, not industry-standard nicotine liquid.

After decades of tobacco research which failed to demonstrate adverse effects of nicotine on the developing brain, recent claims to this effect about vaping are not credible. Failing to demonstrate a gateway effect from vaping to smoking, anti-THR campaigners majored on nicotine 'addiction'. However, given the lack of evidence about the physical and psychological harms of nicotine, concerns about 'addiction' belong more to the realm of moral objections than public health. Finally, and without any evidence, it has been claimed that vaping puts users more at risk from COVID-19.

More science doesn't necessarily mean good science

Since 2010 there has been an explosion in the number of studies from all disciplines looking at all aspects of the use of SNP. An internet search reveals that from 2007–2012 only 53 scientific papers were published on vaping. By 2020, the numbers of published papers covering all types of SNP had risen to over 6000. Unfortunately, many of these studies suffer from methodological flaws derived from confirmation bias; laboratory studies which do not reflect the real world of vaping; methodologies inappropriate to the study proposal; associations presented as causal; and recommendations for policy which have little or no relation to the study outcomes. One infamous recent example of confirmation bias, resulting in a journal retraction, was a study from the University of

California claiming vaping caused heart problems among those who were ex-smokers, until it was revealed these heart problems pre-dated vaping.

Image: Robina WEERMEIJER on Unsplash

THR further undermined

Misleading claims of a teenage vaping epidemic, the tragic vaping deaths caused by illicit THC and the advent of COVID-19, have all been readily exploited by anti-THR actors, from 'grassroots' US campaigners through to national and international medical and public health agencies.

There are two overlapping sociological concepts at play. One is the role of the *moral entrepreneur* who seeks to impose their own standpoints on society at large, and the second is *heuristics* or (again) confirmation bias – whereby the public and the press don't bother to check information, but simply accept it on the basis of their gut reaction or past experience.

Moral entrepreneurs can be individuals, religious groups or formal organisations who press for the creation or enforcement of their normative view of the world. Such individuals or groups also hold the power to generate moral panic by expressing the conviction that a threatening social evil exists that must be combated and they are not concerned with the means of achieving their desired outcome.

Moral panics

The anti-THR narrative is that the whole enterprise is a conspiracy on the part of the tobacco industry to create a new generation of nicotine 'addicts' to compensate for falling cigarette sales. In this narrative, little concern is shown for current smokers, whose problems are considered to be self-inflicted, leaving them two options: quit or die.

One of the many dangerous repercussions of overheated and misleading rhetoric about SNP has been the increase in the number of smokers (and also non-smokers and those living with smokers) who now believe SNP are no safer than cigarettes and may even be more dangerous.

The anti-THR activist-academics and officials are believed to be in possession of accurate information and make it available to the public and the media who in turn are

Source: WHO
Anti-vaping campaign image for the WHO's World No Tobacco Day 2020

unlikely to check or challenge the information. There is general antipathy towards the tobacco industry and many non-smokers will view vaping as the same as smoking, either based on existing prejudices or gut reactions and/or because they see people exhaling clouds of 'smoke' in public.

One hand washes the other

Actions against the range of SNP and nicotine *per se* are conveniently conflated under a banner of 'tobacco control' which in most countries has public support.

This has allowed activist NGOs and academics to attract substantial funding from the anti-tobacco multi-billionaire Michael Bloomberg, through Bloomberg Philanthropies (BP). Beneficiaries include US-based NGOs such as the Campaign for Tobacco Free Kids (CTFK), Vital Strategies and a UK-based reporting agency, The Bureau of Investigative Journalism, which uses Bloomberg funds to publish anti-THR stories. Bloomberg also contributed $160m to the US campaign aimed at a general ban on flavoured nicotine liquid.

Beyond the US, Bloomberg funds the International Union against Lung Disease and Tuberculosis (The Union), and in the UK, the University of Bath is funded to manage anti-THR activities through Tobacco Tactics and STOP, whose modus operandi is to launch ad hominem attacks against THR advocates. The WHO Tobacco Free Initiative also enjoys substantial financial support from Bloomberg where the funds these days appear to be deployed in persuading member states to legislate against SNP. Ironically, the beneficiaries of such a strategy will be the multinational tobacco industry for whom SNP represents less than 10 per cent of overall turnover. In fact, tobacco shares in the US and India rose in response to news of proposed bans on SNP in those countries.

Global regulatory responses

At the top of the global regulatory tree sits the WHO FCTC signed and ratified by 182 countries and the EU Tobacco Products Directive (TPD) which is concerned with many aspects of tobacco and SNP regulation within the European Union (EU).

Every two years the FCTC holds a Conference of the Parties (COP) to review the working of the FCTC, attended by signatory state delegates and the 'approved' non-governmental organisations (NGOs) belonging to the Framework Convention Alliance (FCA). The next meeting (COP9) was due to be held in November 2020 but has now been postponed until 2021. This meeting excludes many organisations who support THR or who have received any funding directly or indirectly from tobacco companies.

The EU TPD is undergoing a review and its report is due out in May 2021. A significant input into the evaluation will be the report prepared by the EU Scientific Committee on Health, Environmental and Emerging Risks (SCHEER). The EU review will feed into the deliberations of the COP, where the FCTC Secretariat which administers the treaty, has already been pushing COP delegates to consider advocating more draconian SNP legislation. The likely battle ground will be over the banning of most flavours.

This attack on THR can be seen in the light of the overall failure of the WHO/FCTC and signatory states to control the smoking epidemic and the politically impossible approach of banning the sale of tobacco. Only Bhutan has banned tobacco sales but this is widely ignored. Much is made of new legislation in place in many countries, but LMIC have little of the administrative and judicial structures in place to enforce legislation. Many such countries have internal tensions between government departments, where the domestic tobacco industry is both an important export commodity and a major source of internal revenue. From a public health point of view, many LMIC will have more immediate concerns about infectious disease control than health problems caused by smoking.

Global picture remains mixed

The gradations of SNP control are complex and differ widely between countries. The GSTHR website (www.gsthr.org) has a comprehensive breakdown of the legislative regime in each country.

While control responses around the world are mixed, the emphasis is moving towards a more prohibitionist approach. There seems little doubt that anti-THR hyperbole from the US has had a global influence on policy makers and legislators.

It remains the case that 85 countries have no specific law or regulation regarding nicotine vaping products, and 75 countries regulate the sale of nicotine vaping products; 36 have bans (down from 39 in 2018).

The moves towards encouraging a flavour ban would severely damage the uptake of vaping, as the availability of flavours is an important determinant in encouraging smokers to switch and stay away from cigarettes.

Some good news too

Despite attempts by anti-THR activists to undermine its position on SNP, Public Health England reaffirmed that vaping plays an important role in helping smokers to quit and consequently, health professionals need training in the use of vaping devices. Vaping was specifically mentioned as part of the UK Department of Health target to go smoke free by 2030.

Australian government officials remain in lockstep over continued de facto prohibition. However, in January 2020, after a careful review of the evidence, the Royal Australian College of General Practitioners published new Australian Smoking Cessation Guidelines in January 2020. The Guidelines cautiously endorse vaping nicotine as a quitting aid for smokers who have been unable to quit with the available therapies, if they request help from their doctors to start vaping. This aligns with the 2018 decision by the Royal Australian and New Zealand College of Psychiatrists to acknowledge vaping as less risky than smoking, while the Royal Australasian College of Physicians now accepts the value of vaping as part of a cessation strategy.

Image: Filip MROZ on Unsplash

Judiciaries in Switzerland (2018) and Quebec (2019) have ruled against respective government restrictions on SNP, while the New Zealand government suffered its own judicial defeat in March 2018. Yet the New Zealand government (and that of the Canadian federal government if not necessarily the provinces) appears to be taking a more pragmatic and proportionate response to SNP than in many other countries. Even in the US, the Food and Drug Administration (FDA) has recognised the value of THR by giving marketing approval to the heated tobacco product IQOS and snus as lower risk products over smoking.

Sitting underneath the FDA decision is the substantial scientific and clinical evidence submitted by PMI (IQOS) and Swedish Match USA (snus) which should attract more attention from the scientific and public health communities. The FDA came to its

landmark decisions based on this evidence so it cannot be dismissed on the grounds of its industry provenance.

THR and the right to health

The notion of non-smokers' right to health – especially bystanders and children – underpinned tobacco control developments through the 1980s and 1990s. Those involved in the campaigns, especially in the US, saw themselves as warriors (in relation to the passive smoking hazard) battling the economic and political interests of tobacco companies. Backed by the evidence of the palpable damage caused by smoking and the increasing efforts to ban public smoking, campaigners seized the moral high ground as smokers became the new social pariahs.

The tables have turned; those whose rights now need protecting are those who want to avoid smoking and instead use safer products. Harm reduction as a social movement arose from the work of drugs and HIV activists who focused on the right to health, with nobody left behind.

However, smokers are left behind, primarily those on low incomes living in poverty and deprivation around the world, with no attractive and effective exit routes out of smoking, who smoke the most and consequently suffer most from smoking-related disease and death. The whole panoply of marginalisation, discrimination and isolation accounts for the very high smoking rates within indigenous and LGBTQ+ communities, those in prison, the homeless and those suffering mental health, drug and alcohol problems.

Image: BLVDONE on Adobe Stock

Women are another hidden population. Globally, fewer women smoke than men, but especially in LMIC, men are typically the main breadwinners, leaving more women at home caring for family. Losing an entire family income due to the death of the man from smoking-related disease throws women and their families into what might be an even more precarious economic situation.

Yet the 'nobody left behind' mantra has long been enshrined in international conventions and continues to be so. Harm reduction sits at the intersection between public health and human rights.

Article 12 of the International Covenant on Economic, Social and Cultural Rights, adopted by the United Nations General Assembly on 16 December 1966, states the right of everyone to enjoy the highest attainable standard of physical and mental health.

As a social justice cause, advocating for people who are often among the most disadvantaged and marginalised in society, THR merits its place as a human rights issue.

THR offers a global opportunity for one of the most dramatic public health innovations ever to tackle a non-communicable disease and at minimal cost to governments. In a time of COVID-19 when global health and public finance systems are stretched to breaking point and may not recover for some time, the imperative to drive forward with THR has never been more urgent.

The way forward

For the first time there is now a wide range of positive inducements for people to switch from smoking, rather than just disincentives. THR, through SNP, offers an unprecedented exit strategy that has been shown to be acceptable to smokers and at minimal cost to governments.

Aspirations aside, the reality is that tobacco control could only ever help to reduce harm, so the case for harm reduction has always been inherent in the mission statement for tobacco, except now there is a real-world opportunity to add enormous heft to beneficial public health outcomes.

Conclusions and recommendations

This report focuses on THR and the benefits to public and individual health of having available, affordable, appropriate and acceptable safer alternatives to combustible tobacco products. It also focuses on the rights of smokers who need the opportunity to switch from smoking and those who have chosen safer alternatives.

Image: Google

Conclusions

» Nearly 8 million people die from smoking-related diseases every year.

» Eighty per cent of the world's smokers live in LMIC, but have the least access to affordable SNP.

» A projected one billion people will die from smoking-related diseases by 2100.

» Smoking rates have been falling in more affluent countries for decades, but rates of decline are slowing.

» The global number of smokers has remained unchanged at 1.1 billion since the year 2000, and in some poorer countries this is set to rise due to population growth.

» The immediate way to reduce smoking-related deaths is to focus on current smokers.

» The evidence for SNP demonstrates that they are substantially safer than combustible tobacco, both for smokers and by-standers, and contribute to helping those wishing to stop smoking.

» The adoption of SNP has been consumer-driven with nil, or minimal, cost to governments.

» SNP have the potential to substantially reduce the global toll of death and disease from smoking, and to effect a global public health revolution.

» Progress in the adoption of SNP has been slow. We estimate 98 million people globally use SNP – including 68 million vapers – amounting to only nine per 100 smokers (fewer in LMIC). There is an urgent need to scale up tobacco harm reduction.

» Many well-funded national and international NGOs, public health agencies, and multi-lateral organisations incorrectly view THR as a threat rather than as an opportunity.

» Many US and US-funded organisations have manufactured panics about young people and vaping, about flavours and the outbreak of lung disease, overshadowing the real public health challenge, which is to persuade adult smokers to switch.

» The near-monopoly on international tobacco control funding by US-based foundations – philanthrocapitalism – has distorted international and national responses to smoking. Donor interests often exclude other policy options, producing a hidden but negative impact on health policies, particularly in LMIC.

» The increasingly prohibitionist emphasis risks many consequences, including that current smokers may decide not to switch, current users of SNP may go back to smoking, and the growth of unregulated and potentially unsafe products.

» There continues to be much poorly conducted research and science, which is then spun with an anti-THR message.

» The WHO's MPOWER initiative alone will be insufficient in hastening an end to smoking – the weakest area of achievement is 'O' – offering help – which is also the most expensive for governments.

» Harm reduction is embedded in nearly every field of the WHO's work except tobacco.

» By denying the role of THR, the WHO is working against the principles and practices enshrined in its own pledges for global health promotion and in international conventions relevant to the right to health, including in Article 1 (d) of the FCTC.

» Richer countries have been the main beneficiaries of THR. Many LMIC are left behind, through a combination of prohibitionist policies and the unavailability of appropriate, acceptable and affordable alternatives to combustible tobacco.

» Those most affected by tobacco control policies have been stigmatised and excluded from the policy conversation. Good public health engages affected populations. The slogan "nothing about us without us" is central to THR, as it is to any field in public health.

Recommendations

1. The primary aim of tobacco control should be to offer current smokers suitable exit strategies. The current predicted toll from smoking can only be averted by hastening a switch from smoking by established smokers.

2. Harm reduction should be properly defined by parties to the FCTC to sit alongside demand and supply reduction. It should be applied universally with no person, group, or community being excluded.

3. The WHO must play a lead role in encouraging FCTC signatories to take a more balanced view of the potential for SNP to help encourage a switch away from combustible products. The current interpretation of Article 5.3 of the FCTC is stifling open debate on the merits of SNP. A new and inclusive approach is required, engaging with all stakeholders with no exceptions, to evaluate the merits of new technologies and products, based on scientific principles rather than ideology.

4. Access to SNP should be a right for all potential beneficiaries irrespective of gender, race, social or economic circumstances.

5. Consumer wellbeing should be at the centre of international planning and policy.

6. The Framework Convention Alliance of NGOs should actively engage with the widest range of THR-focused NGOs, including consumer advocacy organisations.

7. Companies making SNP should strive to reach the largest number of smokers globally with appropriate and affordable products.

8. The role of government should be to hasten the switch from smoking, rather than to place obstacles in the way of those who wish to use SNP.

9. No action should be taken which has the consequence of favouring smoking over SNP, such as making SNP harder to obtain and use than cigarettes, or through unfavourable pricing (e.g. through taxes).

10. All those in positions to formulate policy on SNP should take account of the body of current evidence, rather than opting for off-the-shelf recommendations from multi-lateral and philanthropic organisations.

11. Governments should ensure consumer safety in relation to SNP, based on safety standards available through international, regional and national bodies.

12. Smokers have the right to evidence-based information about the potential benefits of switching to SNP.

13. SNP should be controlled and regulated as consumer products, and consumers need to be assured of the quality of the products they are using.

14. Having a choice of flavours in SNP is an important aspect of the decision to switch away from smoking and to avoid relapse. Banning flavours is counter-productive to positive public health outcomes.

15. There is no identified risk of 'passive vaping' to bystanders. Public health communication should explain that vaping is not smoking, and ultimately the decision to control vaping in particular locations should be left to individual organisations and businesses, rather than through blanket prohibition by government bodies.

The two years since the last edition of this report has been a very difficult time for THR.

The estimated 1.1 billion smokers around the world deserve a better deal and better options. We need to hasten the demise of combustibles and encourage the use of safer non-combustible ways of using nicotine. Evidence from several countries shows that the availability of SNP helps people to switch from smoking.

Globally, progress is slow and those using SNP are still a small fraction of those who smoke. Vaping products have only been on the market for about 12 years and HTP much less, although snus use goes back centuries. Historically, changes in nicotine consumption take some decades. The last disruptive innovation was the invention of the tobacco rolling machine back in the 1880s, but it took around 60 years for the machine-rolled cigarette to oust most other forms of tobacco use in richer countries.

However, we can't wait 60 years. We know that SNP are just that – safer than getting nicotine by burning tobacco. We know that people want to use these products. We have proof from many countries that THR works.

The obstacles are rich foundations with a myopic view of tobacco control, and international organisations wedded to a narrow view of what can be done. There's too much fear, hatred and vested interest in this field. These organisations are rapidly finding themselves on the wrong side of history. There needs to be much more ambition about what can be done, and a healthy dose of compassion.

During the 1980s, public health policies broadened in scope beyond the control of infectious diseases, to wider considerations of prevention through health promotion. In November 1986, the WHO convened the First International Conference on Health Promotion, held in Ottawa, Canada. From that emerged a five-page document called the Ottawa Charter, which defined health promotion,

> *"as the process of enabling people to increase control over, and to improve, their health"*.

It went on to highlight that,

> *"Health promotion focuses on achieving equity in health. Health promotion action aims at reducing differences in current health status and ensuring equal opportunities and resources...People cannot achieve their fullest health potential unless they are able to take control of those things which determine their health"*.

Pledges made by the participants in the Conference included:

> » *"to counteract the pressures towards harmful products"*.
> » *"to respond to the health gap within and between societies, and to tackle the inequities in health produced by the rules and practices of these societies"*.
> » *"to acknowledge people as the main health resource, to support and enable them to keep themselves, their families and friends healthy"*.

Tobacco harm reduction is good public health and health promotion, starting with the people who matter: smokers and those who have chosen alternatives. It's change driven from community level upwards – because it's people who do harm reduction, not experts.

About the report

This is the second edition of the Global State of Tobacco Harm Reduction report first published in 2018. The report takes its inspiration from the Global State of Harm Reduction published by Harm Reduction International (HRI). Also published biennially, the HRI report tracks progress in the introduction of drug harm reduction interventions such as opioid substitute therapy, needle exchange and overdose prevention facilities, also known as drug consumption rooms.

In the same vein, this report maps progress (or otherwise) in global, regional and national change in the availability and use of SNP, the changing regulatory response together with the latest evidence on safer nicotine products and health. We focus too on those the report calls 'the left behind' – groups and communities all over the world who smoke at much higher levels than the rest of society to cope with a multiplicity of economic, social and personal problems. As the environment for THR has grown ever more toxic since our last report, we have turned our attention this time to the mechanisms of the well-orchestrated and well-funded global campaigning driving an increasingly prohibitionist response to SNP.

The information in the report will be useful to policymakers, policy analysts, consumers, legislators, civil society and multi-lateral organisations, media, public health workers, academics and clinicians as well as manufacturers and distributors.

Readers are encouraged to refer back to the previous report for some of the background information omitted this time around. Go to: www.gsthr.org/report/full-report-online

Terminology

There are several terms for tobacco harm reduction (THR) products including alternative nicotine products, new or novel nicotine products, modified or reduced risk products, less harmful, lower risk or less risky products and electronic nicotine delivery systems (ENDS).

This report uses the term **safer nicotine products** (SNP) as a collective expression for vaping, heated tobacco devices and Swedish style snus and some other safer forms of smokeless tobacco. We justify this on the basis that the evidence demonstrates these products present a lower risk than combustible tobacco products by a substantial margin.

Beyond issues of semantic convenience is the issue of technical accuracy. Unlike the previous report, unless quoting other sources, we are not using the term 'e-cigarette', instead using **vaping devices or products**. While 'e-cigarette' is a term in common use and readily understood, it is too easily confused with the idea of smoking a cigarette; many misleading public health communications refer to the dangers of 'smoking e-cigarettes'. The most important innovation of vaping devices is they specifically do not emit dangerous toxic smoke, but substantially safer vapour.

Following the same principle, we have decided on the term **vitamin E-related lung injury (VITERLI)** rather than the more commonly understood EVALI (E-cigarette or Vaping Lung Injury), which incorrectly links the outbreak of lung injury to vaping nicotine liquid. The report also now refers to heated tobacco devices or products (HTP) as opposed to heat-not-burn devices or products.

Data limitations

All efforts have been made to present the most up to date and coherent data across all the sections of this report. However, there are numerous gaps and caveats to be highlighted:

» There is a dearth of information on the prevalence of use of SNP, and in countries that conduct surveys there have been few updates since 2018.
» Many countries do not have adequate information on smoking prevalence and health outcomes.
» Much consumer, market and product data does not appear in the public domain – it is not released by companies as it is deemed commercially sensitive, and is often only available at high cost from market analysis companies.

The GSTHR website

Back in 2018, when the first GSTHR was published, we also launched the world's first website dedicated to providing a global overview of tobacco harm reduction as it relates to the use of safer nicotine products. Since then www.gsthr.org has been substantially improved combining original features with a new suite of options.

Overall, all the narrative and data on the website has been configured to be accessible on computers and mobile devices.

A key feature of the upgraded website are 200+ country profiles which provide data on smoking prevalence and mortality alongside SNP data highlighting, for example all the regulations and controls appertaining to SNP in that country. Moreover, users can call-up on screen comparison data for different countries – and unlike other websites providing data on smoking which can be two years or more out of date, the GSTHR team constantly monitor global data and update the site in real time while also enabling data to be compared over time. Each profile also contains current in-country news about THR developments.

The site is configured to allow users to create maps and charts from the data while all the illustrative material (excluding photos) is freely available to be downloaded for use in conference and seminar presentations and for research and policy documents, for example.

Readers are encouraged to sign up to the website to receive notifications of the latest developments.

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Forewords

Samrat Chowdhery
President of the International Network of Nicotine Consumer Organisations

Nearly two decades into the WHO-led war on tobacco, death rates from smoking are on the increase in some countries, highlighting the need to address gaps in implementation and approach. Yet, as this report reveals, we are witnessing further derailment, propped up by a few private parties with a prohibitionist worldview and deep pockets to see it through. Instead of a course correction, a new front has been opened against harm reduction principles that were borne out of the earlier failed wars against substance abuse.

Caught in the crossfire are over a billion tobacco users who, despite paying the highest taxes and suffering the gravest consequences, find themselves without a voice, a platform for redressal, or support. Offering help to consumers remains the most under-implemented of WHO's tobacco control measures, while the framing of the tobacco war in the broadest terms denies them representation under the pretext of excluding the tobacco industry.

That over 80 per cent of the users are in low- and middle-income countries with meagre means to deal with tobacco-related consequences – the largest vulnerable group on the planet by any measure – the focus ought to be unwaveringly on harm prevention by allowing them to exercise the choice of avoiding death and disease by switching to affordable and accessible risk-reduced alternatives should they feel unwilling or unable to quit.

In fact, the opposite is happening. Since the first edition of this global report in 2018, the climate for tobacco harm reduction has worsened, its legitimacy questioned on weak scientific grounds, and progress stunted with a moral panic that diverts from the laudable goal of limiting tobacco death and disease to actively limiting access to safer products – through bans in low- and middle-income countries and restrictions on flavours, a key switching aid, in developed nations.

The silver lining is that millions of smokers have transitioned to lower-risk products in little over a decade, which puts to rest doubts about their effectiveness and also indicates the willingness of users to take proactive measures to protect their health. But as the report notes, this is still a small step given the large number of users globally, and continued demonisation of tobacco harm reduction alternatives could well turn the tide against them.

This report is as much a record of the adoption of harm reduction policies across the globe as it is a snapshot of the efforts to oppose them.

Fiona Patten
Leader of the Reason Party, and a Member of the Victorian Legislative Council for the Northern Metropolitan Region, Australia

Facts matter and when it comes to harm reduction measures aimed fairly and squarely at fighting the global disaster that is preventable deaths from smoking, they matter more than ever.

This report maps the progress that has been made around the world in the availability of safer nicotine products (SNP), the regulatory response and the latest scientific and

clinical data regarding the efficacy of alternatives to combustible cigarettes.

Incredibly there are people and organisations in the community that seek to peddle 'alternative facts' under the policy banner of tobacco regulation. Their misguided efforts ignore the basic right of everyone to health care options – and that includes those across our society who, for a variety of reasons, have engaged in risky behaviours. It's not for us to judge. The job of governments and health organisations around the world is simple, reduce health risks and improve the overall health of citizens.

Australia was once a leader in harm reduction as well as effective tobacco regulation, but we are desperately falling behind because we are ignoring the facts. Our stagnant smoking rates are evidence of this. Government support for clean needles and methadone is universal here in Australia but these same governments prohibit products proven to reduce the harms of nicotine addiction. Sadly, they have chosen to ignore the facts. Why?

My theory is that nicotine addiction is considered more of a personal choice than, say, an addiction to heroin. Somehow you should have the willpower to just say no to smoking and maybe SNPs make it look easy. Quitting should be hard, they believe. It should be painful. This attitude ignores the economic savings that tobacco harm reduction delivers, ignores the research and ignores the evidence. It ignores the facts and it literally kills people. On top of this our anti-cancer councils want to ban vaping as a SNP while being funded by the nation's largest tobacco retailers. Go figure.

I commend this report and live in hope that more countries including Australia will appear in a more positive light in the next report.

Ethan Nadelmann
Founder and Former Executive Director (2000–2017) of the Drug Policy Alliance

It's a shame that a report such as this, grounded as it is in a deep regard for science, health and human rights, must be produced by a non-governmental organisation. But just as Harm Reduction International realised years ago that it must take on the task of producing its Global State of Harm Reduction report because the United Nations Office on Drugs and Crime and other international and governmental organisations were not willing to produce such a report, so this document reflects the failure of WHO, the Centers for Disease Control and Prevention and other governmental agencies to address honestly the evidence on tobacco harm reduction.

The global war on (illicit) drugs was driven, and is driven still, by a combination of ignorance, fear, prejudice and profit. The problem was not just that public and political opinion so often diverged from scientific and other empirical evidence but also that government agencies, powerful philanthropies and even scientists themselves were blinded and corrupted by abstinence ideologies, anti-drug propaganda and the politicisation of funding for research and treatment. Even many liberal politicians abandoned their commitments to science, compassion and human rights, and scientists dependent on government funding developed political blinders that evolved into intellectual blinders. The results, most now concede, were disastrous not just for those who use drugs illicitly but for societies at large.

Harm reduction must play at least as central a role in tobacco control as it increasingly does in illicit drug control if the number of people dying from tobacco-related illnesses is to decline dramatically. But public policies are moving more backwards than forwards of late, driven in part by governmental agencies and philanthropic advocacy

organisations that shamelessly deceive the public. Nowhere is this more evident than in public opinion surveys showing significant increases in the number of people who incorrectly believe that e-cigarettes and other harm reduction devices equal or exceed the dangers of combustible cigarettes.

No one should trust Big Tobacco, given not just their notorious history but also the fact that their bottom line will always prioritise profit over health given the demands of market competition and shareholder interests. The tobacco control advocates who have fought most valiantly against Big Tobacco are now divided. On one side are those, now amply funded by governments and wealthy philanthropists, who seek to transform a science-based health campaign to reduce cigarette smoking into a poorly conceived campaign to demonise virtually all nicotine products, no matter how much less dangerous than combustible products. On the other are those truly committed to harm reduction principles and the overriding objective of reducing the harms associated with both tobacco use and tobacco control policies. This report honours them.

Abbreviations and acronyms

AFNOR – Association Française de Normalisation

ANSA – EU Agency Network for Scientific Advice

ASH – Action on Smoking and Health (UK)

BMGF – Bill and Melinda Gates Foundation

BP – Bloomberg Philanthropies

BSI – British Standards Institute

CBD – Cannabidiol

CDC – Center for Disease Control and Prevention (US)

CDER – Center for Drug Evaluation and Research (US)

CEN – European Committee for Standardisation

COP – Conference of the Parties – WHO Framework Convention on Tobacco Control

COT – Committee on Toxicity, Carcinogenicity and Mutagenicity of Chemicals in Food, Consumer Products and the Environment (UK)

CTFK – Campaign for Tobacco Free Kids (US)

CTP – Center for Tobacco Products (US)

DG SANTE – Directorate-General for Health and Food Safety (EU)

DOTS – Directly-observed therapy short course

ENDS – Electronic nicotine delivery systems

ERS – European Respiratory Society

ESTOC – European Smokeless Tobacco Council

EVALI – E-cigarette or vaping product use-associated lung injury

FCTC – WHO Framework Convention on Tobacco Control

FDA – US Food and Drug Administration

GBD – Global Burden of Diseases, Injuries and Risk Factor Study

GDP – Gross Domestic Product

GSTHR – The Global State of Tobacco Harm Reduction

HNB – Heat-not-burn

HSS – Department of Health and Human Services (US)

HTP – Heated tobacco products

HPHCs – Harmful and potentially harmful constituents

IARC – International Agency for Research on Cancer

ISO – International Organisation for Standardisation

LMIC – Low and middle-income countries

MHRA – Medicines and Healthcare products Regulatory Agency (UK)

MPOWER – Monitoring-Protect-Offer-Warn-Enforce-Raise (taxes)

MRTPA – Modified Risk Tobacco Product Application

MSA – Master Settlement Agreement

NCCDPHP – National Center for Chronic Disease Prevention and Health Promotion (US)

NCD – Non-communicable diseases

NGO – Non-governmental organisation

NIH – National Institutes of Health (US)

NRT – Nicotine replacement therapy

NYCHD – New York City Health Department

NYU – New York University

ONDIEH – Office of Non-Communicable Disease, Injury and Environmental Health (US)

OSI – Open Society Institute

ONS – Office for National Statistics (UK)

OSH – Office for Smoking and Health (US)

PAHs – Polycyclic aromatic hydrocarbons

PHA – Public Health Association (New Zealand)

PHE – Public Health England (UK)

PMTA – Pre-Market Tobacco Application (US)

RCP – Royal College of Physicians (UK)

RDTA – Rebuildable dripping tank atomiser

RWJF – Robert Wood Johnson Foundation

SCENIHR – Scientific Committee on Emerging and Newly Identified Health Risks (EU)

SCHEER – Scientific Committee on Health, Environmental and Emerging Risks (EU)

SEATCA – Southeast Asia Tobacco Control Alliance

SITRPS – Schroeder Institute for Tobacco Research and Policy Studies

SLAM – South London and Maudsley NHS Foundation Trust (UK)

SNP – Safer nicotine products

ST – Smokeless tobacco

STOP – STOP Tobacco Organisations and Products

STP – Smokeless tobacco products

TFI – WHO Tobacco Free Initiative

THC – Tetrahydrocannabinol

THR – Tobacco harm reduction

TI – Truth Initiative

TobRegNet – WHO Study Group on Tobacco Product Regulation

TPD – Tobacco Products Directive (EU)

TPSAC – Tobacco Products Scientific Advisory Committee (US)

TSNAs – Tobacco-specific nitrosamines

TT – Tobacco Tactics

VITERLI – Vitamin E-related lung injury

VS – Vital Strategies

WHO – World Health Organization

WLF – World Lung Foundation

Introduction

Image: Sajjad ZABIHI on Unsplash

Harm reduction refers to a range of pragmatic policies, regulations and actions which either reduce health risks by providing safer forms of products or substances, or encourage less risky behaviours. Harm reduction does not focus primarily on the eradication of products or behaviours.

Consider road safety. Many countries now have rules about wearing seat belts. Modern cars are designed with airbags which protect us in the event of a crash. Riders in many countries are required to wear cycle or motorbike helmets. Roads have speed limits. We don't ban cars and bikes in case they cause harm to us or others. We adopt these measures to reduce harm, although they are called 'health and safety' rather than 'harm reduction'.

In the context of this report, harm reduction has a more important aspect: a role in championing social justice and human rights for people who are often among the most disadvantaged, stigmatised and marginalised in society.

Advocates for harm reduction argue that people should not forfeit their rights to health if they are undertaking potentially risky activities like drug or alcohol use, sexual activity or smoking.

This more political dimension to harm reduction grew out of the HIV/AIDS epidemic of the 1980s. At-risk and marginalised members of the gay and drug-using communities in the US and Europe acted in support of their own right to health, providing condoms and sterile injecting equipment to their communities in advance of more official interventions and endorsements at both a national and (eventually) at an international level.

The public health impact was undeniable; those countries who embraced harm reduction saw significant falls in HIV rates among affected communities. High risk populations benefited, but so too did the general population.

While the campaign to encourage the spread of drug harm reduction interventions globally is far from won, many countries have now accepted the validity of the approach. Many people who use drugs can now access opioid substitute therapy, needle and syringe programmes and overdose prevention facilities (or drug

consumption rooms). Making these interventions available helps combat drug-related disease and risk of overdose, as well as helping preserve the lives of individuals who may be contemplating leaving drug use behind – or who can at least live better with it.

When applied in a social justice context, harm reduction responses should:

» Be pragmatic, accepting that substance use and sexual behaviour are part of our world and choosing to work to minimise harmful outcomes rather than simply ignore or condemn them.
» Focus on and target potential harms rather than trying to eradicate the product or the behaviour.
» Be non-judgemental, non-coercive and non-stigmatising.
» Acknowledge that some behaviours are safer than others and offer healthier alternatives.
» Facilitate changes in behaviour by provision of information, services and resources.
» Ensure that affected individuals and communities have a voice in the creation of programmes and policies designed to serve them; encapsulated in the slogan, "Nothing about us without us".
» Recognise that the realities of poverty, class, racism, social isolation, and other social inequalities affect people's vulnerability and capacity for dealing with health-related harms.[1]

While harm reduction as a social movement is relatively new, what affected communities have always been fighting for – the right to health, with nobody left behind – has long been enshrined in international conventions and continues to be so. Harm reduction sits at the intersection between public health and human rights.

Support for THR spans the political spectrum. Libertarians abhor the heavy-handed intrusion of government into the lives of smokers wishing to switch to safer products by the imposition of legislative obstacles. Supporters of social justice are very conscious that the main victims of opposition to THR are the disadvantaged – those on low incomes, people struggling with mental illness or alcohol and drug problems, homeless people, indigenous groups and prisoners. The universal right to health is just that – health for everyone.

Tobacco harm reduction – origins

Pioneer – Mike Russell
"Smokers cannot easily stop smoking because they are addicted to nicotine... People smoke for nicotine but they die from the tar"
1976 MBJ 1: 1430-1433

'Rebalancing the market in favour of the safest nicotine products would provide choice, encourage safer nicotine use, and mortality'
p240
Harm reduction in smoking can be achieved by providing smokers with safer sources of nicotine that are acceptable and effective cigarette substitutes.'
p241

Harm reduction in nicotine addiction
Helping people who can't quit

At the time apart from NRT (and snus) no attractive and viable sources of safer nicotine

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[1] *Principles of Harm Reduction*. (n.d.). Harm Reduction Coalition. Retrieved 23 August 2020, from https://harmreduction.org/about-us/principles-of-harm-reduction/

From the early 1980s, medical interventions were available to reduce smoking – nicotine replacement therapy (NRT) and prescription medicines often used in combination with behavioural therapy as part of formal smoking cessation programmes. The advent of vaping devices in the mid-2000s opened up new public health possibilities, affording prominence to other smokeless products such as Swedish snus and US smokeless as part of a new THR paradigm.

Most smokers say they want to stop smoking (or at least wish they wanted to stop). Many quit smoking by gradually reducing or going 'cold turkey', with various rates of success. As Mark Twain said, "Giving up smoking is the easiest thing in the world. I know because I've done it thousands of times". Many though find it hard to stop as they are unable or unwilling to give up nicotine and stick with the combustible cigarette – one of the most dangerous of all nicotine delivery systems.

Harm reduction products have greatly expanded the choice for consumers who wish to continue to enjoy nicotine without the risks inherent in cigarettes or who are looking for a more acceptable way to quit smoking than provided by various medical and psychosocial approaches. Quitting smoking using SNP is pleasurable for most smokers rather than burdensome. It also provides government with an additional tool to replace harms from smoking alongside measures to reduce supply and demand such as tobacco taxes, age restrictions, advertising restrictions and bans on smoking in public places.

Image: DedMityay on Adobe Stock

The technological advances in nicotine delivery have been accompanied in some countries by developments and changes in the profile of manufacturers and distributors, product innovation, investment in research and development, and a market driven by product availability and consumer choice. This, in turn, has raised challenges for governments in terms of appropriate regulatory models, resulting in conflicts between the aims of international tobacco control and the individual right to health.

Professor Michael Russell – consultant psychiatrist, Institute of Psychiatry, London

"The case is advanced for selected nicotine replacement products to be made as palatable and acceptable as possible and actively promoted on the open market to enable them to compete with tobacco products. There will also need to be health authority endorsement, tax advantages and support from the anti-smoking movement if tobacco use is to be gradually phased out altogether.

It is essential for policymakers to understand and accept that people would not use tobacco unless it contained nicotine and that they are more likely to give it up if a reasonably pleasant and less harmful alternative source of nicotine is available. It is nicotine that people cannot easily do without, not tobacco.

It will be assumed … our main concern is to reduce tobacco-related diseases and that moral objections to the recreational and even addictive use of the drug can be discounted providing it is not physically, psychologically or socially harmful to the users or to others."[2]

The starting point for all should be the global epidemic of smoking – which is the subject of the next chapter.

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[2] Russell, M.A.H. (1991). The future of nicotine replacement. *British Journal of Addiction*, 86(5), 653–658. https://doi.org/10.1111/j.1360-0443.1991.tb01825.x

Chapter 1
Smoking: the slow-burning killer

Wherever you sit in the debate about THR there is no denying the statistics on global smoking are grim.

Progress in helping people shift away from smoking is slow. Globally, levels of smoking have hardly changed since our 2018 report. There continue, however, to be some positive changes in a few countries, linked to the uptake of SNP which we discuss in the next chapter.

Smoking is one of the world's biggest health problems:

» Half of all those who smoke will die prematurely from smoking-related diseases.
» The Global Burden of Disease study estimates that smoking accounted for 7.1 million premature deaths in 2017, with an additional 1.2 million deaths attributed to second-hand smoke.[3] This makes it the second highest risk factor for death behind high blood pressure.
» Thirteen per cent of global deaths were attributed directly to smoking in 2017, and a further two per cent due to second-hand smoke.[4]
» Three times more people die prematurely from smoking than from the total combined deaths from malaria (405,000 in 2018)[5], HIV (770,000)[6] and TB (1.5 million)[7].

3

three times more people die from a smoking-related disease than from malaria, HIV and TB combined.

1 billion

the estimated number of smoking-related deaths by 2100 – equivalent to the deaths of the whole populations of Indonesia, Brazil, Bangladesh, Nigeria and the Philippines.

Image: Swapnil DWIVEDI on Unsplash

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[3] Reitsma, M. B. et al. (2017). Smoking prevalence and attributable disease burden in 195 countries and territories, 1990–2015: a systematic analysis from the Global Burden of Disease Study 2015. *The Lancet*, 389(10082), 1885–1906. https://doi.org/10.1016/S0140-6736(17)30819-X
[4] Ritchie, H., & Roser, M. (2013). Smoking. *Our World in Data*. https://ourworldindata.org/smoking
[5] *Fact sheet about Malaria*. (n.d.). Retrieved 23 August 2020, from https://www.who.int/news-room/fact-sheets/detail/malaria
[6] *WHO | Number of deaths due to HIV*. (n.d.). WHO; World Health Organization. Retrieved 23 August 2020, from http://www.who.int/gho/hiv/epidemic_status/deaths/en/
[7] *Tuberculosis* (TB). (n.d.). Retrieved 23 August 2020, from https://www.who.int/news-room/fact-sheets/detail/tuberculosis

The WHO estimates that, based on current forecasts, one billion people will have succumbed to a smoking-related disease by the end of this century.[8] That's equivalent to the whole populations of Indonesia, Brazil, Nigeria, Bangladesh and the Philippines dying from COVID-19.

Burning tobacco is the most common way to ingest nicotine. Cigarettes make up about 89 per cent of tobacco products by sales value, and all combustible products combined comprise 96 per cent of the nicotine market by retail sales value (see also Chapter 2). These other forms of combustible tobacco products include cigars, kreteks (clove cigarettes favoured in Indonesia), bidis (hand-rolled cigarettes popular in South East Asia) and shisha (smoking tobacco filtered through water in waterpipes, found in many Middle Eastern countries).

The WHO indicates a further 346 million adults use smokeless tobacco products worldwide. The majority (about 86 per cent) of smokeless tobacco consumers live in southeast Asia. There is however a wide range of smokeless products with different risk profiles. 'Smokeless tobacco' is a misleading and confusing term when applied to Asian tobaccos which contain several hazardous products, in addition to tobacco. In this report, unless otherwise indicated, we define those safer smokeless tobacco products as US smokeless and Swedish snus type manufactured products.

Nicotine is one of the world's most widely consumed drugs alongside caffeine and alcohol.[9] Smoking is ubiquitous, but 80 per cent of deaths related to smoking occur in LMIC,[10] which in turn comprise about 85 per cent of the global population.

Smoking is not disappearing. There are as many smokers in 2020 as there were in 2000, when it was estimated that there were 1.1 billion smokers. The WHO projects that it will remain at around 1.1 billion until at least 2025.[11] Population growth has offset the decline in the proportion of smokers in the population.

Nicotine is one of the world's most widely consumed drugs alongside caffeine and alcohol.

1.1 billion

the estimated number of smokers globally, unchanged since the year 2000.

Number of adult tobacco smokers by WHO region, 2000–2025 (projected)
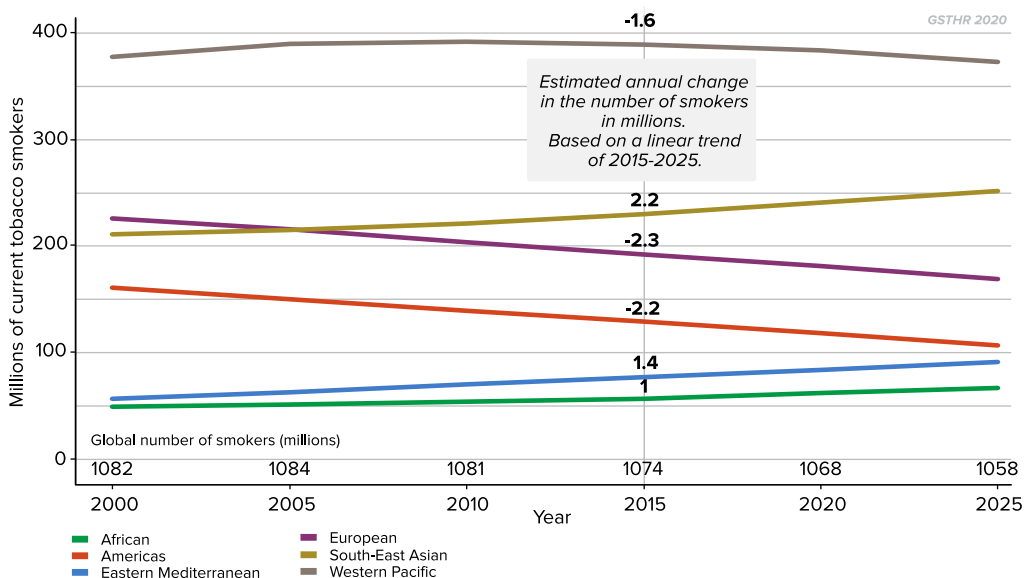
GSTHR 2020

Estimated annual change in the number of smokers in millions. Based on a linear trend of 2015-2025.

-1.6
2.2
-2.3
-2.2
1.4
1

Global number of smokers (millions)

| 1082 | 1084 | 1081 | 1074 | 1068 | 1058 |

| 2000 | 2005 | 2010 | 2015 | 2020 | 2025 |

Year

Millions of current tobacco smokers

- African
- Americas
- Eastern Mediterranean
- European
- South-East Asian
- Western Pacific

WHO global report on trends in prevalence of tobacco use 2000–2025, third edition. (2019). World Health Organization. https://www.who.int/publications/i/item/who-global-report-on-trends-in-prevalence-of-tobacco-use-2000-2025-third-edition

8   Hitti, M. (n.d.). *1 Billion Tobacco Deaths This Century?* WebMD. Retrieved 23 August 2020, from https://www.webmd.com/smoking-cessation/news/20080207/1-billion-tobacco-deaths-this-century

9   Crocq, M.-A. (2003). Alcohol, nicotine, caffeine, and mental disorders. *Dialogues in Clinical Neuroscience*, 5, 175–185.

10 Anderson, C. L. et al. (2016). Tobacco control progress in low and middle income countries in comparison to high income countries. *International Journal of Environmental Research and Public Health*, 13(10). https://doi.org/10.3390/ijerph13101039

11 *WHO Global Report on Trends in Prevalence of Tobacco Use 2000–2025, third edition*. (2019). World Health Organization. https://www.who.int/publications/i/item/who-global-report-on-trends-in-prevalence-of-tobacco-use-2000-2025-third--edition

Some regions now have more smokers than in 2000 and are projected to have even more by 2025, including the African, Eastern Mediterranean, and South East Asian regions. The absolute number of smokers is declining in the European region, the Western Pacific and the Americas.

Which countries currently have the highest levels of daily adult smoking?

Around one in five adults (19 per cent) in the world smokes tobacco.[12]

Many countries have much higher levels of smoking. There are 22 countries where 30 per cent or more of the overall adult population are current smokers. This includes Pacific islands such as Kiribati and the Solomon Islands, several European countries including Serbia, Greece, Bulgaria, Latvia and Cyprus, Lebanon in the Middle East, and Chile in South America.

Go to https://gsthr.org/countries for country-level information on smoking.

It is worth recalling that such high levels of smoking were not uncommon in many countries in the past: for example, in the UK in the mid-1970s, 46 per cent of adults smoked.

Around the world high levels persist, despite major global initiatives led by WHO to reduce smoking – and despite the investment of millions of dollars in tobacco control to reduce the demand for and supply of tobacco (See Chapter 5).

Average levels of smoking at a national level hide significant differences in the levels of smoking between males and females. Almost one third of men (30 per cent) globally smoke compared with 10 per cent of women.[13]

Countries with the smallest and largest difference between levels of adult tobacco smoking for males and females
Current tobacco smoking, age standardized 2018 point estimations.
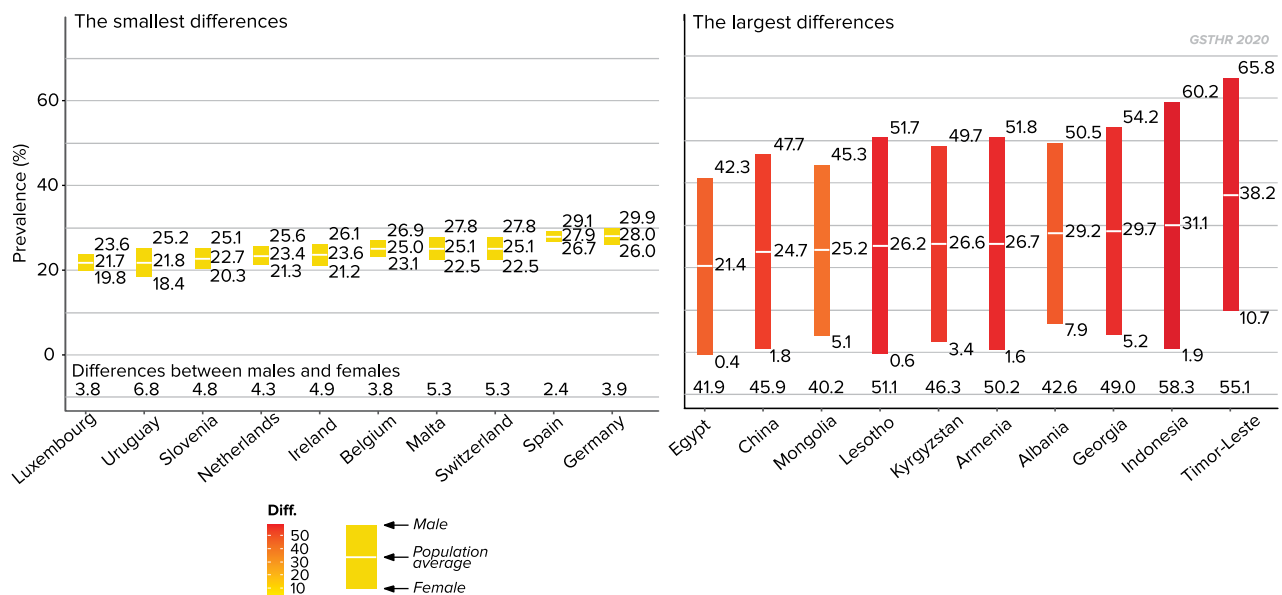
WHO global report on trends in prevalence of tobacco use 2000–2025, third edition. (2019). World Health Organization. https://www.who.int/publications/i/item/who-global-report-on-trends-in-prevalence-of-tobacco-use-2000-2025-third-edition

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12 Ritchie, H., & Roser, M. (2013). Smoking. *Our World in Data*. https://ourworldindata.org/smoking#share-who-smoke

13 *WHO global report on trends in prevalence of tobacco use 2000–2025, third edition*. (2019). World Health Organization. https://www.who.int/publications/i/item/who-global-report-on-trends-in-prevalence-of-tobacco-use-2000-2025-third-edition

According to WHO data for 2018, the prevalence of current tobacco smoking among men in 35 countries is above 40 per cent. This ranges from a staggering 69 per cent in Kiribati, to 50 per cent in in Albania, Cyprus, Kyrgyzstan and Latvia, 45 per cent in Greece, Mongolia and Republic of Moldova and 41 per cent in Ukraine, the Russian Federation, Bangladesh and Samoa.[14]

In a few high-prevalence countries, the level of female smoking is higher than the male smoking levels found in lower prevalence countries for example, in Kiribati, Nauru, Chile and Serbia, over 40 per cent of women smoke compared to 78 other countries where less than 30 per cent of men smoke.

In some indigenous communities, such as the Māori, more women smoke than men (see Chapter 7). There is some evidence that for cultural or social reasons in some countries, there may be under-reporting of female smoking.[17,18]

Which countries have the most smokers?

Nearly half the world's smokers (46 per cent) live in just three countries.

China has the largest number of current smokers at 290 million, followed by India at 116 million and Indonesia at 61 million. Together, these countries account for 467 million smokers.

Countries with the highest number of current tobacco smokers
Population 2018, 15+

China	290 M
India	116 M
Indonesia	61 M
USA	53 M
Russian Federation	34 M
Bangladesh	24 M
Japan	24 M
Pakistan	23 M
Brazil	22 M
Germany	20 M

467 million smokers
46% of global smokers

GSTHR 2020

Millions

■ Male
■ Female

5 globally, over five times as many men smoke as women. [15,16]
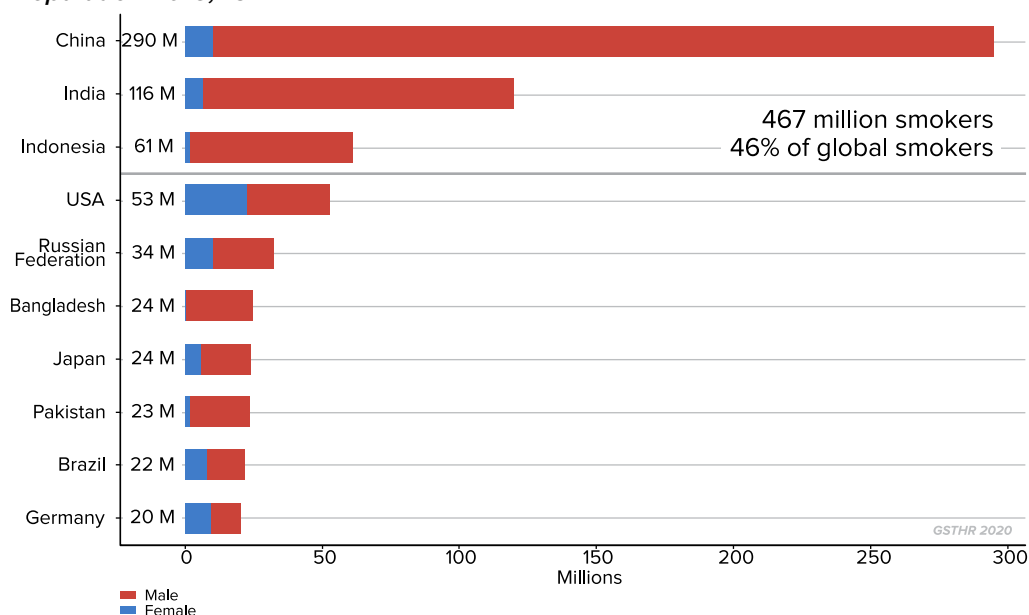
467 million smokers – nearly half the global total – live in just three countries: China, India and Indonesia.

WHO global report on trends in prevalence of tobacco use 2000–2025, third edition. (2019). World Health Organization. https://www.who.int/publications/i/item/who-global-report-on-trends-in-prevalence-of-tobacco-use-2000-2025-third-edition
Department of Economic and Social Affairs (Ed.). (2019). *World Population Prospects 2019* (Online Edition Rev. 1.; Population Division). United Nations. https://population.un.org/wpp/Download/Standard/Population/

[14]　Countries where 40 per cent or more adult males smoke: 69 per cent in Kiribati; 66 per cent in Timor-Leste; 60 per cent in Indonesia; 56 per cent in Solomon Islands; 54 per cent in Georgia; 52 per cent in Tuvalu, Armenia and Lesotho; 50 per cent in Albania, Cyprus, Kyrgyzstan and Latvia; 49 per cent in Chile; 48 per cent in Lao People's Democratic Republic, Tonga and China; 46 per cent in Bosnia and Herzegovina and Nauru; 45 per cent in Greece, Mongolia and Republic of Moldova; 43 per cent in Belarus, Tunisia and Malaysia; 42 per cent in Bulgaria, Egypt, Fiji, Kazakhstan, Philippines and Turkey; 41 per cent in Ukraine, Russian Federation, Bangladesh and Samoa.

[15]　*WHO global report on trends in prevalence of tobacco use 2000–2025, third edition.* (2019). World Health Organization. https://www.who.int/publications/i/item/who-global-report-on-trends-in-prevalence-of-tobacco-use-2000-2025-third-edition.
[16]　Department of Economic and Social Affairs (Ed.). (2019). World Population Prospects 2019 (Online Edition Rev. 1.; Population Division). United Nations. https://population.un.org/wpp/Download/Standard/Population/
[17]　Roth, M. A. et al. (2009). Under-reporting of tobacco use among Bangladeshi women in England. *Journal of Public Health*, 31(3), 326–334. https://doi.org/10.1093/pubmed/fdp060.
[18]　Li, H. C. W. et al. (2015). Smoking among Hong Kong Chinese women: Behavior, attitudes and experience. *BMC Public Health*, 15(1), 183. https://doi.org/10.1186/s12889-015-1529-4. Increasing smoking rates among women could be a hidden dimension to the smoking epidemic. For example, smoking among Hong Kong women rose over 70 per cent from 1990–2012.

What are the trends in smoking?

Historically, most countries have seen a rise and then a decline in smoking. Sales of cigarettes took off around the year 1900 in richer countries, peaked by the 1980s and have since declined.[19] A general decline in rates of smoking is apparent across all global regions, and for both sexes.

Tobacco smoking prevalence, 2000–2025 (projected)
Females and males, age-standardized average for WHO regions
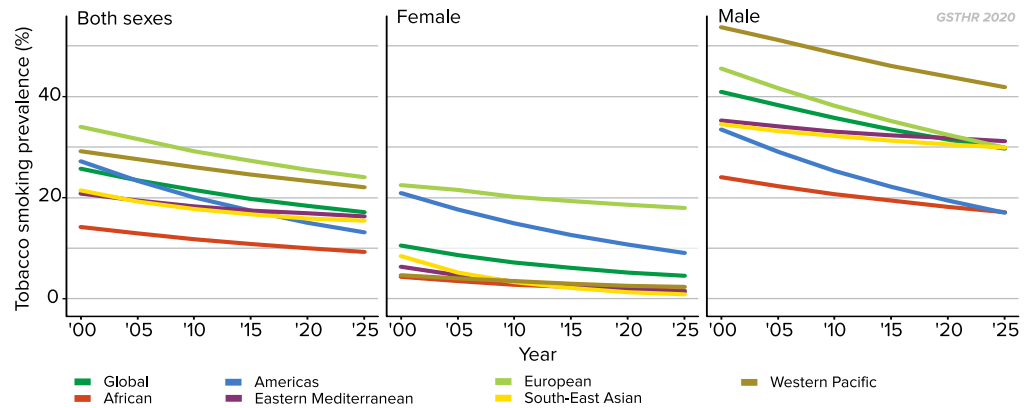
WHO global report on trends in prevalence of tobacco use 2000–2025, third edition. (2019). World Health Organization. https://www.who.int/publications/i/item/who-global-report-on-trends-in-prevalence-of-tobacco-use-2000-2025-third-edition

This has been especially marked in many higher-income countries. Rates of smoking have fallen for both men and women largely due to greater public awareness of the importance of a healthier lifestyle, as well as the introduction of various tobacco control measures including advertising bans, smoke-free environments, and higher taxation. Nevertheless, reduction in smoking prevalence tends to start plateauing at around 20% of a population, suggesting diminishing returns on tobacco control interventions. In the chart, we group countries in terms of the drop in the prevalence of current tobacco smoking, from those countries with the highest drop in prevalence to those with the lowest drop. Across all groups there tends to be a levelling at around 20 per cent.

2000–2020 prevalence of tobacco smoking
Countries grouped from the highest to lowest drops in percent prevalence
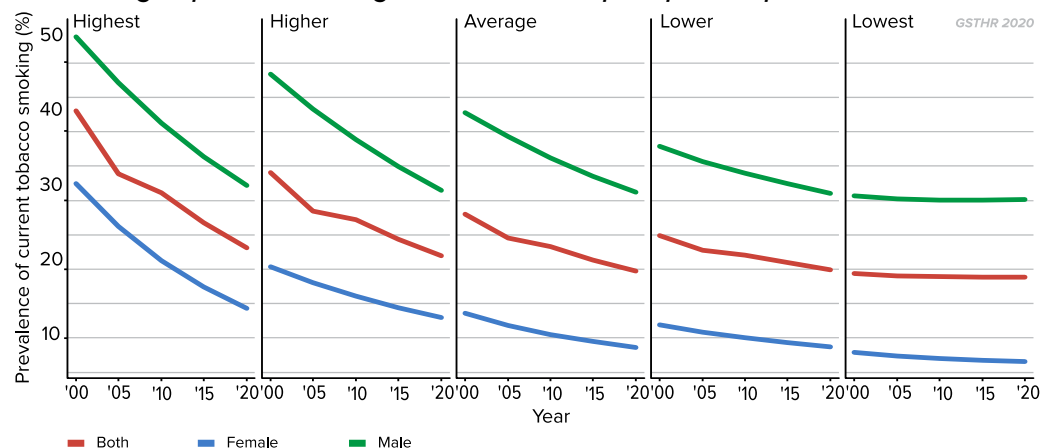
WHO global report on trends in prevalence of tobacco use 2000–2025, third edition. (2019). World Health Organization. https://www.who.int/publications/i/item/who-global-report-on-trends-in-prevalence-of-tobacco-use-2000-2025-third-edition

What these data show is that millions of people are still smoking, many of whom will want to, but have been unable, to quit. We discuss this in later chapters, where we

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19   Hoffman, S. J. et al. (2019). Impact of the WHO Framework Convention on Tobacco Control on global cigarette consumption: quasi-experimental evaluations using interrupted time series analysis and in-sample forecast event modelling. *BMJ*, 365. https://doi.org/10.1136/bmj.l2287

consider the limits of tobacco control interventions and the need to adopt harm reduction measures for people who don't want to smoke but want to continue using nicotine.

However, it is not all bad news. There are some notable exceptions – countries which fall well below the 20 per cent marker. This is particularly noticeable in countries where SNP are replacing combustible tobacco such as the UK, Sweden and Norway.

Reductions in smoking levels are to be welcomed, but progress is slow. The WHO set aspirations for the global reduction of tobacco use (both smoking and smokeless tobacco) by 30% between 2010 and 2025.[20] Globally, the WHO estimates that only 32 out of 149 countries (for which measures are available) are likely to achieve this.

4 in 5

the number of countries that will not meet WHO target reductions in smoking by 2025.

Levels of smoking-related mortality remain high

Slow progress means that deaths from smoking remain high. This is linked both to the current prevalence of smoking, and the legacy of smoking in previous years. There are 27 countries where 20 per cent or more of deaths are attributable to smoking.

Countries with the highest levels of mortality attributable to smoking tobacco
(over 20% of all deaths)

Country	Mortality (%)
Korea, North	31.72
Bosnia and Herzegovina	25.05
Montenegro	25.02
Armenia	24.76
Turkey	22.59
Bangladesh	22.18
Vietnam	22.03
Belarus	22.03
China	21.94
Hungary	21.85
Albania	21.77
Tunisia	21.61
Denmark	21.53
Macedonia	21.16
Netherlands	21.11
Poland	21.04
Russian Federation	20.88
Greece	20.87
Cuba	20.82
Kazakhstan	20.8
Ukraine	20.65
Mongolia	20.46
Azerbaijan	20.37
Malaysia	20.2
Serbia	20.05
Georgia	20.04
Kiribati	20.03

GSTHR 2020

Drope, J. et al. (2018). *The Tobacco Atlas* (6th ed.). American Cancer Society and Vital Strategies.

In addition to the huge human toll of illness and death there is the enormous cost to the global economy. Considering both direct costs of hospital care and medication, and indirect costs of lost productivity, it has been calculated that the annual global cost of smoking-related disease and death amounts to $1.4 trillion.[21] Extrapolated to the end of the century, the figure comes to $112 trillion. According to the 2019 World Bank data, this is $24 trillion more than current annual global GDP.[22]

$1.4 trillion

the estimated annual global cost of smoking.

[20] *WHO | Global Action Plan for the Prevention and Control of NCDs 2013-2020*. (n.d.). WHO; World Health Organization. Retrieved 23 August 2020, from http://www.who.int/nmh/events/ncd_action_plan/en/
[21] Goodchild, M. et al. (2018). Global economic cost of smoking-attributable diseases. *Tobacco Control*, 27(1), 58–64. https://doi.org/10.1136/tobaccocontrol-2016-053305
[22] List of countries by GDP (nominal). (2020). *In Wikipedia*. https://en.wikipedia.org/w/index.php?title=List_of_countries_by_GDP_(nominal)&oldid=974300848

Global smoking trends and global tobacco policy

The trends in smoking are in the right direction, but by any metric progress is slow: the question is, what could speed it up?

The WHO makes much of the extent to which tobacco control measures have been introduced in many countries. While it laments slow progress on reducing the prevalence of smoking, the overarching message from the WHO is that its global tobacco control strategy is working, as more countries adopt tobacco control measures, for example, at a legislative level.

Yet passing legislation through a parliament is one thing. Enforcing the law is a different matter in countries which lack the necessary administrative, financial and enforcement resources, not to mention the political will, to do so. This lack of will is not confined to those countries with a vibrant tobacco agriculture; even on health grounds, officials in Africa, for example would prioritise dealing with infectious diseases over tobacco control.

The degree to which countries can implement and enforce policies rather than simply signing up to good intentions is notably split between high income countries and LMIC. As the authors of *The global tobacco control 'Endgame'* point out, effective national implementation of the provisions of the 2005 FCTC to which most countries signed up is very much dependent on the overall public health climate.

> *"We identify the most relevant characteristics of the policy processes within 'leading' countries with the most comprehensive tobacco control: their department of health has taken the policy lead (replacing trade and treasury departments); tobacco is 'framed' as a pressing public health problem (not an economic good); public health groups are more consulted (often at the expense of tobacco companies); socioeconomic conditions (including the value of tobacco taxation, and public attitudes to tobacco control) are conducive to policy change; and, the scientific evidence on the harmful effects of smoking and second-hand smoking are 'set in stone' within governments. These factors tend to be absent in the countries with limited controls. We argue that, in the absence of these wider changes in their policy environments, the countries most reliant on the FCTC are currently the least able to implement it."* [23,24]

The WHO asserts that the slow progress towards reducing smoking levels in poorer countries is because the introduction of strong tobacco control policies in these countries has been impeded by lobbying from the tobacco industry. It also cites, somewhat more obscurely, "setbacks, unexpected barriers...and difficult political barriers to overcome." [25]

There is a wider global concern here which relates to the UN 2030 Agenda for Sustainable Development. The preamble states that, "This Agenda is a plan of action for people, planet and prosperity. It also seeks to strengthen universal peace in larger freedom. We recognize that eradicating poverty in all its forms and dimensions, including extreme poverty, is the greatest global challenge and an indispensable requirement for sustainable development", and that "nobody will be left behind". [26]

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[23] Cairney, P., & Mamudu, H. (2014). The global tobacco control 'Endgame': Change the policy environment to implement the FCTC. *Journal of Public Health Policy*, 35(4), 506-517.

[24] There are also some serious questions to be raised about the funding of tobacco control programmes in Africa – see Chapter 5.

[25] *WHO Report on the Global Tobacco Epidemic 2019.* (2019). World Health Organization. https://www.who.int/tobacco/global_report/en/, p. 60

[26] *Transforming our World: The 2030 Agenda for Sustainable Development* (A/RES/70/1). (2015). United Nations. https://sustainabledevelopment.un.org/post2015/transformingourworld/publication, p. 5

Goal 3 of the agenda is to "ensure healthy lives and promote well-being for all at all ages" with a target (3.4) of reducing premature deaths from non-communicable diseases (NCD) by one third by 2030. But as the recent WHO NCD report notes, "Country actions against NCDs are uneven at best. National investments remain woefully small and not enough funds are being mobilized internationally... There is no excuse for inaction, as we have evidence-based solutions." (WHO, 2018)

The top three causes of NCD mortality are cardiovascular disease, cancer and respiratory disease; all closely associated with cigarette smoking. When the American Cancer Society published the first edition of the Tobacco Atlas in 2002, the authors wrote, "The publication of this Atlas marks a critical time in the epidemic. We stand at the crossroads with the future in our hands." In the fifth edition (2015) they added, "These words are as true today as they were then."

The Atlas authors wrote about standing at the crossroads. Now, the promise of THR has carved out a new path to take. Back in 2002, smokers had just two roads to choose from: which has been caricatured as a choice between 'Quit' or 'Die'. The main thrust of tobacco control strategy has been to make smoking less attractive to and more difficult for smokers, focusing on supply (industry-related) and demand (consumer-related) interventions.

> **The main thrust of tobacco control is to make smoking less attractive and more difficult for smokers, focusing on supply (industry-related) and demand (consumer-related) interventions.**

In 2007, the WHO launched its MPOWER tobacco control strategy as an implementation guide to the Framework Convention on Tobacco Control (FCTC) which has the following components:

Monitor tobacco use and prevention policies.
Protect people from tobacco smoke.
Offer help to quit tobacco use.
Warn about the dangers of tobacco.
Enforce bans on tobacco advertising, promotion and sponsorship.
Raise taxes on tobacco.

In terms of the health of current smokers, the most important strand is offering help to quit smoking – for example, through the provision of smoking cessation services which smokers can access for little or no charge.

In the 2019 report on the global tobacco epidemic, the WHO admitted: "cessation policies are still among the least implemented of all WHO FCTC demand reduction measures, with only 23 countries in total [out of 195] providing best-practice cessation services, the majority of which are high-income countries." It goes on to say: "if tobacco cessation measures had been adopted at the highest level of achievement in 14 countries between 2007 and 2014, 1.5 million lives could have been saved".[27]

> **MPOWER alone is insufficient: the one in five of the adult population still smoking deserve additional options.**

On the vital question of saving lives then, MPOWER is clearly insufficient. Its implementation by international donors and national and local agencies (see Chapter 5) focuses too much on process and output indicators (the number of countries adopting various measures) rather than outcomes – a decline in smoking.[28] The one in five of the adult population still smoking deserve additional options.

Smokers who cannot or do not wish to either quit or die have a third route to reduce the risk of death or disease. THR, through the use of SNP, has the potential to

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[27] *WHO Report on the Global Tobacco Epidemic 2019*. (2019). World Health Organization. https://www.who.int/tobacco/global_report/en/, p. 10

[28] One study estimated that those countries which had implemented MPOWER to the 'highest levels of achievement' have seen the more rapid falls in smoking levels. But most of those countries cited were in northern Europe and Australia, which had seen significant declines in smoking well before the strategy was in place. Gravely, S. et al. (2017). Implementation of key demand-reduction measures of the WHO Framework Convention on Tobacco Control and change in smoking prevalence in 126 countries: an association study. *The Lancet Public Health*, 2(4), e166–e174. https://doi.org/10.1016/S2468-2667(17)30045-2

substantially reduce the global toll of death and disease from smoking, and to effect a global public health revolution – and all at marginal or no cost to governments. This is now more vital than ever, as the public purse of every nation will be stretched to breaking point attempting to recover from the economic aftershocks of the coronavirus pandemic.

In the development of this alternative to 'quit or die', public health as a body of professional organisations has had little impact. In fact, it is consumers who have led the charge to develop and embrace alternative forms of nicotine, in products that both work and are desirable. Consumers have shown us that it is possible for the world to move away from smoking forever.

Chapter 2
Market forces: products and consumers

> *"Nothing is so painful to the human mind as a great and sudden change."*
>
> *Mary Shelley*

Joseph Schumpeter, one of the most influential economists of the 20th century, is credited with popularising the idea of 'creative destruction' in economics. This refers to a process of "industrial mutation that incessantly revolutionises the economic structure from within, incessantly destroying the old one, incessantly creating a new one". Since Schumpeter wrote this in 1942 for his book *Capitalism, socialism and democracy*, the pace of technological change has increased significantly, making it ever harder for large well-established companies to keep pace.

Image: Jason LEUNG on Unsplash

In their pioneering 1995 article in the *Harvard Business Review*, Joseph Bower and Clayton Christensen wrote that "one of the most consistent patterns in business is the failure of leading companies to stay at the top of their industries when technologies or markets change. Goodyear and Firestone entered the radial-tyre market quite late. Xerox let Canon create the small-copier market. Bucyrus-Erie allowed Caterpillar and Deere to take over the mechanical excavator market. Sears gave way to Wal-Mart."[29]

Bower and Clayton go into more detail on how IBM missed out on the personal computer market. Had they been writing more recently, they might have added Kodak's belief they had nothing to fear from digital cameras, and that Microsoft was way behind the curve on the significance of the internet.

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[29] Bower, J. L., & Christensen, C. M. (1995). *Disruptive Technologies: Catching the Wave*. https://www.hbs.edu/faculty/Pages/item.aspx?num=6841, p.43-53

The mistake many companies make is to stay too close to their mainstream customers, who may have no need for innovation. So Xerox corporate customers had no need for table top photocopiers, any more than IBM's corporate and government mainframe customers saw any need for desktop computers.

Computer mainframe IBM, Computer History Museum, California

In 2013…Goldman Sachs…believed that vaping products had "the potential to transform the tobacco industry"

SNP have been similarly disruptive. In their 2013 Annual Report, Goldman Sachs defined creative disruption as a process that is "driven by product or business model innovation – often abetted by technology – that results in a superior value offering for consumers, be it higher performance, greater convenience or lower cost."[30] Goldman Sachs believed that vaping products had "the potential to transform the tobacco industry." Indeed, as far back as 1958 and as concerns about cigarette safety grew, one tobacco executive remarked that anybody who came up with the 'safe' cigarette would dominate the market.[31]

Referring to the work of Bower and Clayton, Danish business expert Jacob Hasselbalch makes a distinction between disruptive technology and disruptive innovation. He defines disruptive technologies as those which present much better or faster ways of accomplishing a goal. Disruptive innovation, he argues, makes use of new technologies to present end-users with a product or service superior to those currently existing. From this, new markets are created.[32]

Following centuries of tobacco chewing and pipe smoking, the invention of the cigarette in the 19th century was a disruptive technology. Invented by James Bonsack in 1880, the disruptive innovation was the cigarette rolling machine with a production of 200 cigarettes per minute, replacing a workforce of up to fifty people rolling by hand.

[30] Boroujerdi, R. D. (2014). *The search for creative destruction* (pp. 1–5). Goldman Sachs Global Investment Research. https://www.goldmansachs.com/investor-relations/financials/archived/annual-reports/2013-annual-report-files/search.pdf
[31] Parker-Pope, T. (2001, February 10). *'Safer' Cigarettes: A History.* https://www.pbs.org/wgbh/nova/article/safer-cigarettes-history/
[32] Hasselbalch, J. (2014, November 18). *Regulating Disruptive Innovations: The Policy Disruption of Electronic Cigarettes.* Global Reordering: Towards the Next Generation of Scholarship conference, Brussels

Over a ten-hour shift, Bonsack's machine was churning out 700,000 cigarettes a day, laying the ground for the modern tobacco industry.[33]
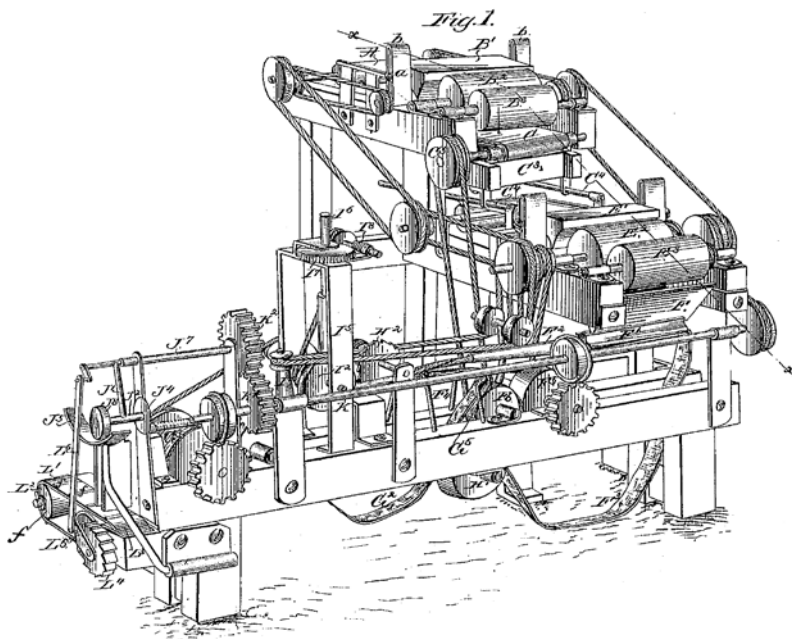
https://commons.wikimedia.org/wiki/File:Bonsack_machine.png

As is so often the case with modern day business disruption, the revolution in making nicotine consumption dramatically safer came from outside the tobacco industry. There were some attempts by the industry to produce a non-combustible nicotine product. All failed, until a Chinese pharmacist Hon Lik patented the first modern e-cigarette in 2003.

An American patent attorney, Mark Weiss, brought Hon Lik's product, the Ruyan, into the US in 2006 and founded NJOY, one of the first companies to manufacture and sell vaping products in the US. Their King product was a classic e-cigarette, disposable with a faux white paper wrapping, a filter and red 'ember' which lit up when drawn on.[34]

For the next five years, the industry grew through word of mouth and the development of online sales. Then in 2012, Lorillard paid an estimated $135m for the main NJOY rival called blu, launched in 2009 by Australian entrepreneur Jason Healy. The vaping business had soared in value over a short space of time, but the entry of major tobacco companies such as Lorillard, Reynolds, and Altria into the fray was a game-changer. These companies had the traditional distribution outlets – and so were able to place the new products right where the smokers were. However, the distribution power of these traditional tobacco companies did not necessarily guarantee successful entry into a market driven by technology and innovation.

In Europe a British businessman, Greg Carson, is credited with introducing what he called the 'Electro Fag' in 2005. Interviewed by the *Daily Mail* in July 2007, Carson said he came across the device on the internet and went to China to investigate: "At first, I was highly sceptical, but I took a trip out there to see it with my own eyes. As a non-smoker it was difficult to form an opinion, but I brought some samples back with me. The reaction has been phenomenal. The product might look simple, but the technology is astonishing." In the UK, the indoor smoking ban came into force on 1st July 2007; Carson imported 1,500 of what the *Daily Mail* called 'fake cigarettes' to beat the ban.[35]

The cigarette rolling machine was a disruptive innovation: one machine churned out 700,000 cigarettes a day, leading to the modern tobacco industry.

"The product might look simple, but the technology is astonishing."

[33] Kruger, R. (1996). *Ashes to Ashes-America's Hundred-Year Cigarette War, the Public Health, and the Unabashed Triumph of Philip Morris*, NY. Alfred A. Knopf. P.19-20

[34] The npro-mini also resembled an early NJOY product. http://www.electroniccigarettereview.com/njoy-review-npro-mini/

[35] Phillips, R. (2007, July 7). *Electriciggy: The battery-powered nicotine fix that helps smokers beat the ban.* Mail Online. https://www.dailymail.co.uk/news/article-466898/Electriciggy-The-battery-powered-nicotine-fix-helps-smokers-beat-ban.html

The article (dated 7 July 2007) described the new device as follows:

> *"The new Electronik cigarette lights up, appears to blow smoke and satisfies the most desperate nicotine craving."*

It included an account from Anna, a smoker, who „roadtested the new invention on a night out in London."

> *Settling myself into a pub off Kensington High Street, I bought myself a glass of wine and took a drag. Nothing happened, so I tried again. This time, I definitely tasted a faint whiff of raspberry-flavoured air. [...] It tasted quite nice, but nothing like a cigarette.*

In 2006, Professor Bernhard-Michael Mayer, a toxicologist at the Karl-Franzens University in Graz, Austria, was approached by Renatus Derler:

> *"He came to my office and showed me a small box lettered in Chinese. It turned out to contain a cigar-type electronic cigarette. Rene discovered this device (made by Ruyan) in China and managed to get the exclusive right for marketing in Europe. [He took out a patent in January 2007]. He asked me for a written expert opinion on the toxicology and potential usefulness of this device for smoking cessation. At that time, I was a heavy smoker and was enthusiastic after the first draw. No surprise, as I had selected the 'strong' variant, which contained 60 mg/ml nicotine. I provided him an overwhelmingly positive report for the Austrian authorities and predicted this device would eradicate smoking within the next 15 years."*[36]

But even before Derler went to see Professor Mayer, the product was in circulation. In April 2005, a Philip Morris lawyer staying in an Italian hotel saw a TV advert claiming this product "tasted like Marlboro".

From the point of view of the history of vaping and tobacco harm reduction, it is interesting that Professor Mayer's report concluded as far back as 2006 that, "since there is no combustion process, ...the health risk is therefore much lower than when tobacco products are consumed."[37]

That small report about an unknown device was the harbinger of a revolution in ways to consume nicotine which inaugurated a global THR movement.

SNP products

Vaping devices

Rapid innovation continues in new nicotine delivery systems. In the 2018 GSTHR report, we went into some detail about the various types of SNP.[38] With respect to vaping devices, the most notable change is the rising popularity of pod systems of various types which offer the portability of the original 'e-cigarette' with the power of larger so-called box mods.

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[36] Professor Mayer. Personal communication.

[37] Mayer, B. Expert opinion on the pharmacology and toxicology of electric cigarette for smoking cessation. Unpublished March 2006.

[39] A recent article in *The Economist* revealed that the Chinese vaping manufacturer Smoore is now the world's most valuable vaping company estimated at $24bn, nearly double the market value of JUUL. But Smoore are likely to face competition from the state-owned China Tobacco Company who are researching the market. Yet another example of the power of disruptive business. A state tobacco monopoly looms over China's e-cigarette makers. (n.d.). *The Economist*. Retrieved 23 August 2020, from https://www.economist.com/business/2020/07/23/a-state-tobacco-monopoly-looms-over-chinas-e-cigarette-makers

Image: lezinav on Adobe Stock

Devices have otherwise remained much the same save for various small refinements to make them more user friendly – top fill tanks are now common, for example, where more awkward bottom fills were previously the norm. Sub-ohming (where large clouds are produced using lots of power) is now less popular as the more demure mouth to lung (MTL) vaping style has seen a comeback, demonstrated by the increasing number of MTL tanks on the market, many of which now have a rebuildable option for people who wish to make their own coils. The global regulatory environment has been responsible for the demise of many independent e-liquid producers and there is also less variety in hardware production, as most of the devices on the market are produced by a handful of manufacturers in Shenzhen, China.[39]

While just another vaping device, in just a few years JUUL has become America's most popular and its most controversial device, so much so that the term 'juuling' has become commonplace alongside 'vaping'. JUUL is a discreet device and can be charged via a USB connection. JUUL uses nicotine salts rather than freebase nicotine liquid, which allows for higher and speedier levels of nicotine delivery similar to that of a combustible cigarette, without the accompanying throat irritation.[40] The nicotine hit and JUUL's compact design account for its popularity.

[40] Hajek, P. et al. (2020). Nicotine delivery and users' reactions to Juul compared with cigarettes and other e-cigarette products. *Addiction*, 115(6), 1141–1148. https://doi.org/10.1111/add.14936

Image: Michael FALLON on Unsplash

Fuelled by a major tobacco company Altria buying a 35 per cent stake in JUUL, the company faced substantial criticism for a marketing campaign aimed at young adults. This prompted claims by anti-vaping groups that JUUL single-handedly created a vaping 'epidemic' among teenagers. As of February 2020, JUUL in America lodged a Pre-Market Tobacco Product Application with the US Food and Drug Administration (FDA) for its standard product and for one which can only be activated through an app-based, government-verified age identification system.

Heated tobacco products (HTP)

https://commons.wikimedia.org/wiki/File:IQOS_-_heated_tobacco_products.jpg

Like vaping devices, there is a back story of industry attempts to bring a successful heated tobacco device to market. Vaping technology was relatively simple, allowing several small start-ups to enter the market. By contrast, the cost of HTP development meant the field has been left to the major tobacco companies who have had the resources necessary to pioneer this technology. IQOS (PMI), Ploom Tech (JTI), glo (BAT) and Pulze (Imperial) were the first to market. However, new players are now joining the

field, such as US companies 3T and Firefly, alongside China Tobacco with their Mok device and Korea Tobacco's lil. The number of countries in which HTP products are sold has increased from 37 (in our 2018 report) to 54.

Smokeless tobacco

Many parts of the world have versions of smokeless tobacco, which can be chewed, inhaled nasally, or placed under the lip.

Tobacco chewing became widespread in the main tobacco growing areas of the American south from the mid-19th century onwards and is still in vogue among some young males in the southern states, although its popularity was already on the wane before the Second World War.

https://commons.wikimedia.org/wiki/File:Dipping_tobacco,_miscellaneous_brands.jpg

Dipping tobacco is a type of finely ground or shredded, moistened smokeless tobacco product. It is used by placing a lump, pinch, or 'dip' of tobacco between the lip and the gum. This evolved into modern day moist snuff, with Copenhagen introduced in 1822, and Skoal introduced in the US in 1934, betraying the Scandinavian roots of this type of smokeless, oral tobacco product. Dipping tobacco is typically flavoured, most commonly with mint and wintergreen, but also grape, cherry, apple, orange, lemon/citrus, peach and watermelon.

The largest markets for US-type smokeless tobacco and snus (excluding Asian smokeless) in dollar terms are the US, Sweden and Norway.

Snus

Swedish snus is a moist smokeless tobacco product, made from ground tobacco leaves and food-approved additives. Among all the smokeless tobacco products, snus has captured most attention, because of its success in reducing the prevalence of lung cancer and other tobacco-related diseases in Sweden.[41] Today, the dominant snus brands come in small teabag-like sachets which users insert in the mouth, often under the upper lip.

The number of countries in which HTP products are sold has increased from

37

(in our 2018 report) to

54

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[41] Foulds, J. et al. (2003). Effect of smokeless tobacco (snus) on smoking and public health in Sweden. *Tobacco Control*, 12(4), 349–359. https://doi.org/10.1136/tc.12.4.349

Snus production involves processes which decrease both the microbial activity and level of carcinogenic tobacco-specific nitrosamines in the final product. Production changes introduced over the past few decades by the major manufacturers have resulted in reducing levels of unwanted substances in Swedish snus still further.

The nicotine content of snus varies between brands, with the most common strength being 8 mg of nicotine per gram of tobacco while stronger varieties may contain up to 22 mg of nicotine per gram of tobacco.

Non-tobacco nicotine pouches

With vaping products coming under increasing political and legislative threat in many countries, a new product category is emerging with several major tobacco companies now selling 'tobacco-free' nicotine pouches. These products are sold as pre-portioned pouches similar to snus, but instead of containing tobacco leaf, they are filled with white nicotine-containing powder and come in a variety of flavours with a nicotine content ranging from 2–7mg. The pouches are placed between the lip and gum and require no spitting or refrigeration.

https://commons.wikimedia.org/wiki/File:ZoneX_nicotine_pouches.jpg

There are various brands currently on the market in different countries. Dryft is owned by Kretek International and sold in the US. British American Tobacco market Lyft in the UK, Sweden and Kenya. The nicotine content for Lyft is 4 and 6 mg. In 2019, British American Tobacco started selling nicotine pouches in Kenya. In Sweden, Switzerland and the UK, consumers can buy Nordic Spirit sold by Japan Tobacco International. Altria purchased 80% of the On! nicotine pouch company, the product being sold in Sweden, Japan and the US. The R.J Reynolds Vapor Company produce Velo, Imperial Tobacco have their own brand Zone X sold in the UK, while Swedish Match have Zyn, sold in Europe and the US.

THR and smokeless products

Beyond the safer products listed above, especially in India and East Asia, there are varieties of smokeless products containing other, potentially dangerous compounds in addition to tobacco.

With different names such as paan and gutkha, the betel/araca nut combination is found right across the region, in India, Pakistan, Indonesia, the Philippines, Taiwan, Myanmar, Cambodia, Laos and Vietnam and also reaching these communities the world over. With or without tobacco, these forms of smokeless tobacco products present a risk of oral and other cancers. This could be significantly reduced, if not obviated, by a switch to snus-style pouches.

SNP: global markets and consumers

So, what has been the impact of these new and longer established products in terms of consumer uptake of SNP?

Establishing accurate data for markets in SNP isn't easy. Much of the information that is collected is retained by companies manufacturing these products, online sellers and by market research analysts. The information is not freely available in the public domain. However, this information is important for public health analysis and should be shared.

The global market in nicotine

The global nicotine market was estimated to be worth approximately $785 billion in 2017, including all tobacco products, vapour products and NRT products. Cigarettes make up 89 per cent of the nicotine market by sales value, and in 2017, all combustible products together (cigarettes, cigars and cigarillos, and rolling tobacco) comprise 96 per cent of the nicotine market by retail sales value.[42]

The six largest tobacco companies dominate the nicotine market with China National Tobacco Corporation being the largest producer in 2017 having 38 per cent of the volume share (calculated by cigarette stick equivalents) followed by British American Tobacco and Philip Morris International (each 13 per cent), Japan Tobacco Inc (9 per cent), Imperial brands (4 per cent) and Altria Group Inc (3 per cent).

Non-combustible products were globally still a small part of the nicotine market in 2017 – at about 4 per cent. Smokeless tobacco products comprised around 1.6 per cent, vaping systems 1.5 per cent, HTP 0.8 per cent and NRT 0.3 per cent.

Cigarette sales volumes are declining at about 2 per cent a year. By comparison, vapour products have shown the biggest increases in recent years although from a very small base.

Globally, the value of the vaping market has continued to grow since our 2018 report and is projected to grow further. The chart from Statista[43] shows the value of the e-cigarette market at around $19bn and its steady projected growth from 2012 through to 2023. Market values are commonly quoted by market research companies, but because they are based on retail sales by large manufacturers and through major commercial outlets, they underestimate sales from smaller retailers, specialist vape shops and online sellers.

The highest number of vapers live in the United States, China, Russian Federation. United Kingdom, France, Japan, Germany and Mexico.

The US is the world's biggest vaping market. Vaping products account for somewhere between 5-10 per cent of the tobacco market (excluding sales from smaller outlets noted above) and for about 70 per cent of the global market in new pod mod systems.

96 per cent

the percentage of nicotine sold as combustible products (cigarettes, cigars, cigarillos, rolling tobacco). The dirtiest nicotine delivery system – cigarettes – dominates at 89 per cent.

4 per cent

the percentage of nicotine by value sold in 2017 as non-combustible products – smokeless tobacco, vapes, heated tobacco, NRT.

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[42] *Global Trends in Nicotine.* (2018). Foundation for a Smoke-Free World. https://www.smokefreeworld.org/advancing-industry-transformation/global-trends-nicotine/
[43] *E-Cigarettes - worldwide | Statista Market Forecast (adjusted for expected impact of COVID-19).* (2020, May). Statista. https://www.statista.com/outlook/50040000/100/e-cigarettes/worldwide

Worldwide revenue in the e-cigarette market
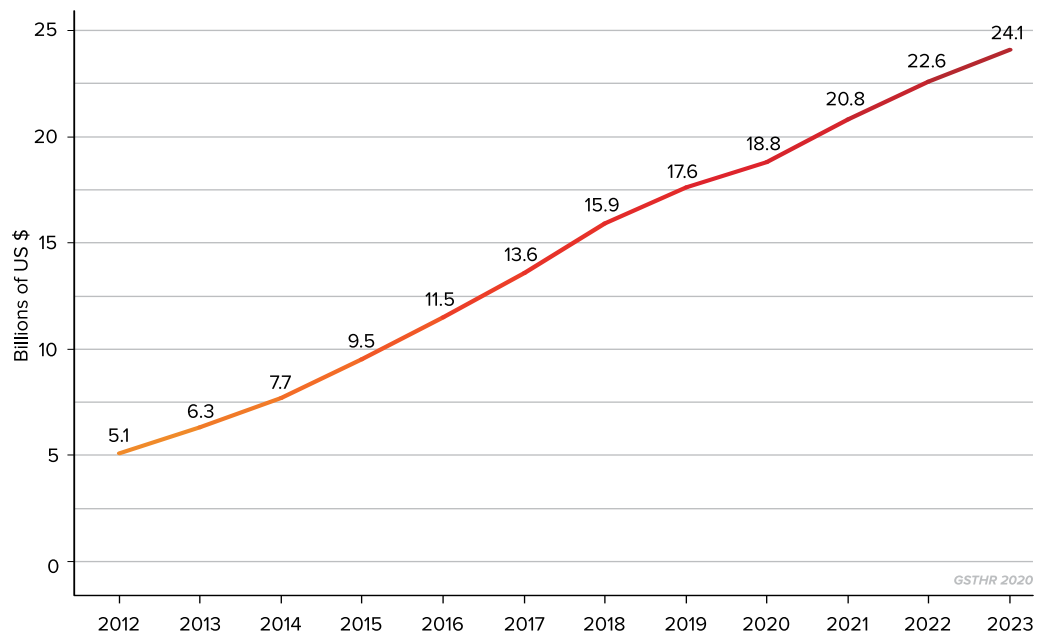
E-Cigarettes – worldwide | Statista Market Forecast (adjusted for expected impact of COVID-19). (2020, May). Statista. https://www.statista.com/outlook/50040000/100/e-cigarettes/worldwide

The share of the vaping market owned by tobacco companies remains small. Tobacco companies are estimated to have less than 20 per cent market share of the global vaping market. In France, Italy, Germany and most other markets it is less than 10 per cent; in the USA and Russia it is around 20 per cent, and estimated to be highest in the UK (33 per cent) and Poland at around 50 per cent. In China, it is zero per cent.[44]

Tobacco companies have less than 20 per cent share of the global vaping market.

Japan dominates the market in HTP with smaller but growing markets in over 50 other countries.

In the light of a more adversarial atmosphere in the US towards vaping products and eager not to endure a Kodak moment, all the major tobacco companies have now brought non-tobacco nicotine products to market.

Most market estimates predict continued growth but there are concerns about the impact of misinformation about teen vaping, scares about vaping-related lung injury and deaths, COVID-19 and the increasingly belligerent attitude towards SNP among legislators.

So, how many people are using these products?

Global use of SNP

There is no clear way to translate market data into numbers of people globally using SNP.

Companies are interested in market numbers and value. Market data can report trends in dollar values and units sold. But from a public health perspective what is important is the numbers of people using different SNP, how this compares with smoking, and trends in both smoking and SNP use over time. This information can only be gained from population surveys. Given the health, economic and political significance of SNP, it is surprising how little information there is concerning the number of people using them. The dearth of data creates problems for those charged with making regulatory decisions and undertaking public health analysis.

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44 Personal communication. Tim Phillips, ECigIntelligence.

The market analysis company Euromonitor estimated in 2011 that 7 million people were regular dual or sole users of vaping products around the world. That estimate rose to 35 million in 2016 and 40 million in 2018 and was predicted to rise to around 55 million by 2021.[45]

Image: Mauro MORA on Unsplash

The GSTHR estimate of the number of nicotine vapers globally

We have made the first attempt to estimate the global prevalence of vaping. This has been based on national prevalence surveys where available. Data were available for various years between 2011 and 2019 for 49 countries.

68 million

the estimated number of vapers globally.

Estimated trends in the worldwide number of vapers

The trend lines were calculated on the basis of GSTHR Global Number of Vapers Estimation from June 2020 and STATISTA data on global revenues in the e-cigarette market from May 2020 assuming a 93% linear relationship between the value of the e-cigarette market and the number of users.

Global number of vapers estimate for 2018

Projection of global number of vapers for 2020

Number of vapes (millions)

Global estimation values: 21.3 M, 25.4 M, 30.1 M, 36.3 M, 43.1 M, 50.3 M, 58.1 M, 63.9 M, 68.0 M, 74.8 M, 81.0 M, 86.1 M

Countries with surveys values: 14.8 M, 17.6 M, 20.9 M, 25.2 M, 29.9 M, 34.9 M, 40.3 M, 44.4 M, 47.2 M, 51.9 M, 56.2 M, 59.7 M

Years: 2012, 2013, 2014, 2015, 2016, 2017, 2018, 2019, 2020, 2021, 2022, 2023

GSTHR 2020

Population
- Global estimation
- Countries with surveys

GSTHR 2020
E-Cigarettes – worldwide | Statista Market Forecast (adjusted for expected impact of COVID-19). (2020, May). Statista. https://www.statista.com/outlook/50040000/100/e-cigarettes/worldwide

[45] *Global Tobacco: Key Findings Part II: Vapour Products | Market Research Report | Euromonitor* (Strategy Briefing). (2017). Euromonitor International. https://www.euromonitor.com/global-tobacco-key-findings-part-ii-vapour-products/report, p.11

Where national data were unavailable, we have used an accepted epidemiological method of estimating country data of assumed similarity with other countries in the same region for which data points are available. This methodology is commonly used for estimating health status in the absence of national surveys; it may be less reliable for estimating consumer behaviour. We adjusted by World Bank income classifications. We have also adjusted figures according to the legal status of vaping products, adjusting prevalence downwards for states where these are not legal. Given that the vaping market has increased since many of the surveys were conducted, we made a market value correction. We further undertook a reality check with key correspondents for selected countries, especially for those with high estimated numbers. Details of our methods can be found in the Annex (page 151).

Based on this approach we estimate that as of 2020 there were 68 million vapers globally. A lower estimate, based only on the 49 countries for which survey data are available, is over 47 million.

Estimated number of HTP users globally

It is harder to estimate the number of HTP users given the paucity of national data. We have therefore had to rely on manufacturers estimates.

The April 2020 investor report from Philip Morris International[46] indicates 14.6 million IQOS users, of whom approximately 10 million are "converted" users, defined as people that used IQOS for over 95 per cent of their daily tobacco consumption over the past seven days. Market analyst estimates suggest 10 million HTP users in Japan and 20-25 million globally.[47]

We have been unable to confirm these estimates from independent sources. Given that there may well be overlap in consumer use of devices from different companies, a conservative estimate is that there may be 20 million users of HTP. (As a reality check, Euromonitor estimates of the vaping market in our first report suggested HTP users constituted about one third the number of vapers[48]).

Estimated number of US smokeless users and snus users

The US National Survey on Drug Use and Health estimates that there are around eight million consumers of smokeless tobacco in the USA,[49] meaning chewing tobacco or snuff on one or more of the previous 30 days. Dissolvable tobacco, dip, and US snus were not measured.[50] Manufacturer data indicate 1 million snus users in Sweden.[51] Market analyst estimates are that there are 1.6 million snus users in the US, Sweden and Norway.[52] Given the paucity of global data and different definitions of 'use' we take a conservative 'guesstimate' of 10 million US smokeless and snus users globally.

[46] *Investor Information.* (2020). Philip Morris International. https://philipmorrisinternational.gcs-web.com/static-files/ d755c6c0-37a2-4eca-b41c-5c43b810520c, slide 67

[47] Personal communication, data and definitions not provided.

[48] https://www.gsthr.org/report/full-report-online#ch04

[49] Brad Rodu. (2014, August 8). *How many Americans use smokeless tobacco?* R Street. https://www.rstreet.org/2014/08/08/ how-many-americans-use-smokeless-tobacco/

[50] CDCTobaccoFree. (2018, August 29). *Smokeless Tobacco Use in the United States.* Centers for Disease Control and Prevention. https://www.cdc.gov/tobacco/data_statistics/fact_sheets/smokeless/use_us/index.htm

[51] *How many snus users are there in Sweden?* (n.d.). Swedish Match. Retrieved 23 August 2020, from https://www. swedishmatch.ch/en/what-is-snus/qa/how-many-snus-users-are-there-in-sweden/

[52] Personal communication, data and definitions not provided.

GSTHR estimate of the numbers globally using all safer nicotine products

We estimate that in addition to the 68 million vapers there might be a further 30 million people globally using other safer nicotine products, defined as HTP, snus and US smokeless, indicating a global total of 98 million people. Given the paucity of data, this estimate should be read cautiously. The current state of published evidence does not allow for a more sophisticated estimate.

Public health and government survey agencies should make better attempts to monitor use of safer nicotine products, and manufacturers of these products should make more transparent the information they collect. Clearly, global consumer interest in SNP has not been matched by government or academic surveys to explore even the extent of use of these products.

Country level data

Our global level estimate is based on extrapolation from national surveys. We have been trying to map the prevalence of vaping on a country basis since 2018 and to date there are only 49 states and territories where we have identified suitably representative data on the prevalence of vaping product use. That is a small change from 2018 when we identified 35 countries with data, and many states and territories have only one data point. In the European Union (EU), the Eurobarometer 2017 survey[53] has not yet been repeated. Few countries are undertaking tracking studies to look at changes in use over time – exceptions being the US and the UK. Readers must be aware of limits to the comparability of the sources. Surveys can suffer from numerous differences, due to variations in sampling methods and questions asked. We therefore suggest caution in making country comparisons.[54] Prevalence data are even scarcer for HTP – we only managed to find information for one country. Data are available and searchable on a country basis on the GSTHR database.[55]

98 million

the estimated number of people globally using safer nicotine products – vaping products, HTP, snus, and US smokeless.

Image: Grispb on Adobe Stock

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[53] *Special Eurobarometer 458: Attitudes of Europeans towards tobacco and electronic cigarettes – European Union Open Data Portal.* (n.d.). Retrieved 23 June 2020, from https://data.europa.eu/euodp/en/data/dataset/S2146_87_1_458_ENG

[54] Farsalinos, K. E. et al. (2016). Electronic cigarette use in the European Union: analysis of a representative sample of 27 460 Europeans from 28 countries. *Addiction*, 111(11), 2032–2040. https://doi.org/10.1111/add.13506

[55] See www.gsthr.org/countries. Larger companies will have detailed sales and consumer data, but these are regarded as commercially sensitive.

[56] *Special Eurobarometer 458: Attitudes of Europeans towards tobacco and electronic cigarettes – European Union Open Data Portal.* (n.d.). Retrieved 23 June 2020, from https://data.europa.eu/euodp/en/data/dataset/S2146_87_1_458_ENG

The average prevalence of current vaping product use is 1.6 per cent of the adult population in the EU, as found in the EU Eurobarometer[56] survey. A further 13 per cent "used to use them, but no longer do so" or "have tried them once or twice". 85.6 per cent "have never tried or used them". Levels of sometime vaping experience range up to 27 per cent of the adult population in Greece, and 20 per cent or above in Estonia, Czech Republic, France, Cyprus, Latvia and Austria. Clearly, there are many smokers who are interested in these products. But there is also a large gap between those who have shown enough interest to have tried vaping at some time, and those who have gone on to currently vape.

Overall, as a percentage of the total adult population, current use of vaping devices in different countries ranges between 1 per cent and 7 per cent.

There are eight countries where the prevalence of vaping is 3 per cent or more including the UK, United Arab Emirates (UAE), US, France, Iceland, Belgium, the Russian Federation and Malaysia.

Prevalence of current smoking cigarettes and current vaping
Countries where the prevalence of vaping is 3% or more

WHO global report on trends in prevalence of tobacco use 2000–2025, third edition. (2019). World Health Organization. https://www.who.int/publications/i/item/who-global-report-on-trends-in-prevalence-of-tobacco-use-2000-2025-third-edition
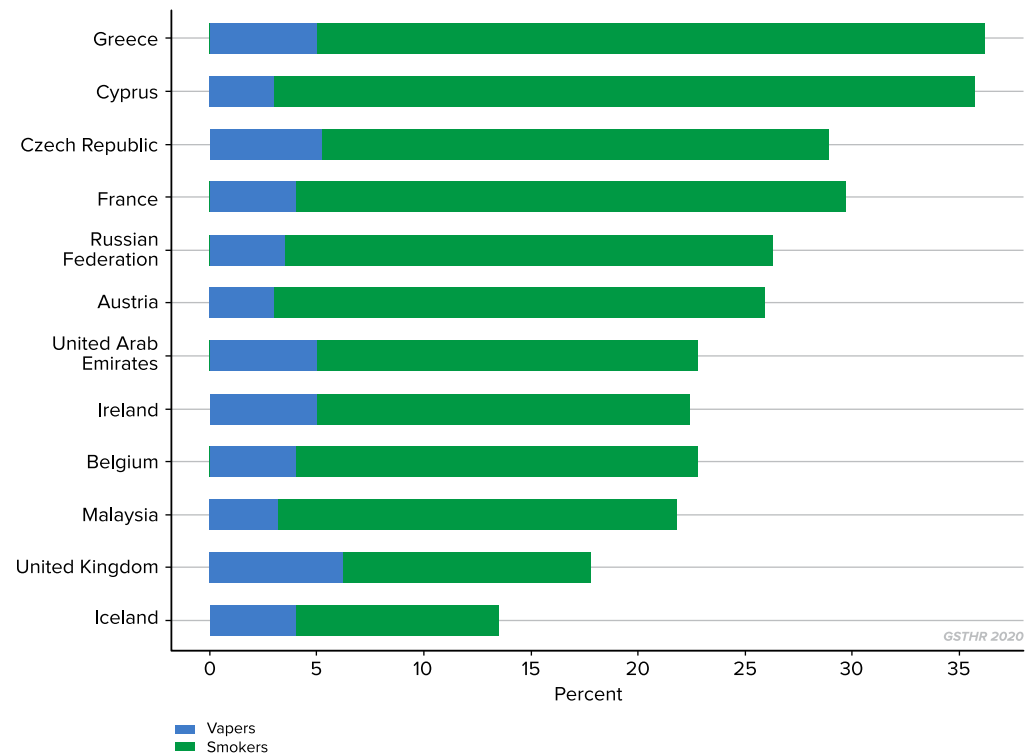*Special Eurobarometer 458: Attitudes of Europeans towards tobacco and electronic cigarettes – European Union Open Data Portal.* (n.d.). Retrieved 23 June 2020, from https://data.europa.eu/euodp/en/data/dataset/S2146_87_1_458_ENG
Farsalinos, K. E. et al. (2018). Electronic cigarette use in Greece: an analysis of a representative population sample in Attica prefecture. *Harm Reduction Journal*, 15(1), 20. https://doi.org/10.1186/s12954-018-0229-7
Vaping Linked to Decrease in Cigarette Smoking (Iceland Directorate of Health Newsletter, reported in Iceland Review). (2018, May 3). *Iceland Review*. https://www.icelandreview.com/news/vaping-linked-decrease-cigarette-smoking/
Healthy Ireland Survey documents. (2019). https://www.gov.ie/en/collection/231c02-healthy-ireland-survey-wave/
McNeill, A. et al. (2020). *Vaping in England: 2020 evidence update summary* (Research and Analysis). Public Health England (PHE). https://www.gov.uk/government/publications/vaping-in-england-evidence-update-march-2020/vaping-in-england-2020-evidence-update-summary

Windows of opportunity

Japan

HTP now account for about a third of tobacco sales.[57,58] There is a consensus around the following factors to account for this phenomenal rise matched against a dramatic fall in cigarettes sales:

» Interest in innovative technologies
» Relatively high levels of disposable income
» A paradoxical legal situation which on the one hand bans vaping products but on the other, not only allows HTP products to be sold, but gives the companies license to advertise and promote widely alongside a favourable tax regime.

Image: Liam BURNETT-BLUE on Unsplash

» A cultural ethic whereby Japanese people are very considerate in health terms such that they embrace HTP over cigarettes as being less polluting and irritating to others. Consumer research in Japan revealed that the top two reasons for switching were not having to worry about unpleasant smells nor affecting others and also that they are less harmful than cigarettes.

32 per cent

the drop in the sales of cigarettes in Japan since the introduction of HTP.

Cigarette and HTP sales in Japan, 2014–2019

GSTHR 2020

32%
57.96 billions of units drop in cigarette sales since the introduction of HTP

Total cigarette sales is an estimation based on JTI sales and JTI market share

-4.1 B -2.2%　-8.7 B -4.7%　-22.3 B -12.8%　-18.9 B -12.5%　-8.1 B -6.1%

Total HTP sales were calculated from the reported market share of PMI HeatSticks.

Sales volume (billions of units) / Percentage annual drop in cigarette sales / Year

Sales volume
■ Cigarette sales
■ PMI HeatSticks
■ Other HTP
■ Total HTP

Japanese domestic cigarette monthly sales results (Information by Business Segment). (2020). Japan Tobacco Inc. https://www.jt.com/investors/results/S_information/domestic_cigarette/index.html
Philip Morris International 2019 Annual Report. (n.d.). Retrieved 16 July 2020, from http://media.corporate-ir.net/media_files/IROL/92/92211/2020-PMI-FinalFiles/index.html

[57] A special issue of the *International Journal of Environmental Research and Public Health* dealt exclusively with aspects of HTP use in Japan including the mapping of cigarette against HTP sales; use of HTP with other products; indoor use of HTP; perceptions of relative risk and use by young people.
IJERPH | Special Issue: Japan: Evaluating the Effectiveness of Tobacco Control Policies and the Use of Heated Tobacco Products. (n.d.). Retrieved 23 August 2020, from https://www.mdpi.com/journal/ijerph/special_issues/Japan_evaluating_effectiveness_tobacco_control_policies_use_heated_tobacco_products#
[58] Cummings, K. M. et al. (2020). What Is Accounting for the Rapid Decline in Cigarette Sales in Japan? *International Journal of Environmental Research and Public Health*, 17(10), 3570. https://doi.org/10.3390/ijerph17103570

UK

Image: Anthony DELANOIX on Unsplash

We noted in our previous report the significant rise in vaping and decline in smoking since 2011. Around 7 per cent of the adult population in Great Britain currently vapes[59], which equates to around 6 million vapers[60]. The year on year increase in vaping is matched by the continuing major reduction in smoking in the UK with under 15 per cent of the adult population currently smoking.

Trends in smoking (UK) and e-cigarette use (Great Britain) 2011–2019
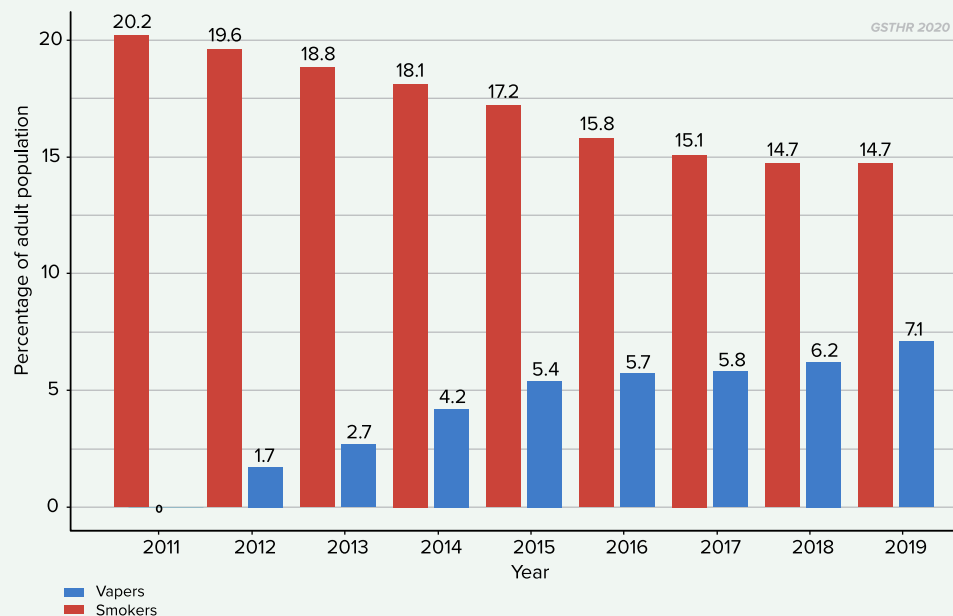
GSTHR 2020

Year	Smokers	Vapers
2011	20.2	0
2012	19.6	1.7
2013	18.8	2.7
2014	18.1	4.2
2015	17.2	5.4
2016	15.8	5.7
2017	15.1	5.8
2018	14.7	6.2
2019	14.7	7.1

Percentage of adult population

■ Vapers
■ Smokers

McNeill, A. et al. (2020). *Vaping in England: 2020 evidence update summary* (Research and Analysis). Public Health England (PHE). https://www.gov.uk/government/publications/vaping-in-england-evidence-update-march-2020/vaping-in-england-2020-evidence-update-summary
Use of e-cigarettes among adults in Great Britain, 2019. (2019). Action on Smoking and Health. https://ash.org.uk/information-and-resources/fact-sheets/statistical/use-of-e-cigarettes-among-adults-in-great-britain-2019/

[59] For an up to date assessment of SNP use in England see; West, R et al. *Trends in electronic cigarette use in England*. Smoking toolkit study 2020. www.smokinginengland.info/latest-statistics
[60] Great Britain is England, Scotland and Wales. The United Kingdom (UK) is England, Scotland, Wales and Northern Ireland – vaping prevalence in the UK is approximately five percent.

Iceland

Iceland has witnessed a dramatic decline in smoking to 8.2% in 2019[61], and has the second lowest adult daily smoking rate in Europe after Sweden.

A long-term secular decline in smoking accelerated in 2007 and again in 2012.

Market data show, on a weight-for-weight basis, a continued decline in cigarette sales and an increase in snus sales.

Prevalence of adult daily snus use was 3.2% in 2012[62] rising to 6% in 2019[63].

Prevalence of adult daily e-cigarette use was 3.6% in 2017.[64]

It would appear that the uptake of snus and latterly of e-cigarettes has contributed to the long-term decline in smoking.

Most significant is that smoking uptake among young people has virtually disappeared with only 3.3% of 18-24 year old smoking, and 0.8% of 16 year olds[65].

Changes in the prevalence of smoking and sales of cigarettes and snus in Iceland

GSTHR 2020
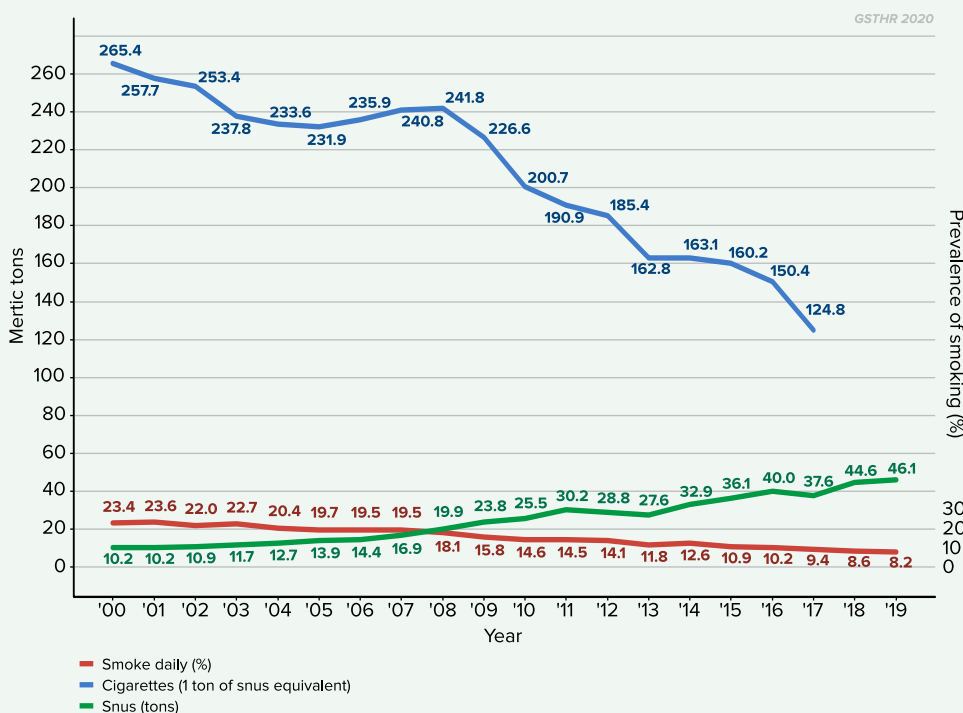
Statistics Iceland | Smoking habits by sex and age 1989-2018 and Allt talnaefni – Statistics.

Notes:
Snus sales from Iceland state alcohol stores https://www-statista-com.iclibezp1.cc.ic.ac.uk/statistics/792450/sales-volume-of-snuff-in-vinbudin-stores-in-iceland/
Cigarette sales based on cartons sold and assuming 0.75g tobacco per cigarette to convert to metric tons.

[61] *Statistics Iceland | Smoking habits by sex and age 1989-2018*. (n.d.). Statistics Iceland. Retrieved 3 September 2020, from https://px.hagstofa.is/pxen/pxweb/en/Samfelag/Samfelag__heilbrigdismal__lifsvenjur_heilsa__1_afengiogreyk/HEI07102.px/?rxid=e93275f5-10ff-46e9-aea7-bd1bc6bee345
[62] *Allt talnaefni – Statistics*. (n.d.). Retrieved 3 September 2020, from https://www.landlaeknir.is/tolfraedi-og-rannsoknir/tolfraedi/allt-talnaefni/, https://www.landlaeknir.is/servlet/file/store93/item35873/31_toba9_Tobak_i_vor_UTGEFID.pdf
[63] Directorate of Health data – personal communication, Karl Snæbjörnsson
[64] *Allt talnaefni – Statistics*. (n.d.). Retrieved 3 September 2020, from https://www.landlaeknir.is/tolfraedi-og-rannsoknir/tolfraedi/allt-talnaefni/, https://www.landlaeknir.is/servlet/file/store93/item35874/33_toba11_Rafsigarettur_UTGEFID.pdf
[65] Directorate of Health data – personal communication, Karl Snæbjörnsson

An unrealised public health success story

What has been lost in all the heat and dust about 'the dangers of vaping' is that the use of SNP is one of the most startling public health success stories of modern times. From a standing start around 2006, many people in many countries around the world have taken control of their own health by switching to non-combustible products or reducing their smoking levels through parallel use.

The health revolution in safer nicotine products has been consumer-driven and comes at minimal cost to governments.

This has been achieved without the intervention of official public health agencies, and often in spite of their best efforts to stop it. Moreover, this public health revolution has been driven by consumers choosing safer nicotine products in preference to combustibles. It has occurred with minimal cost to governments. This is a true bottom up public health success, being driven by a public concerned for their health.

1.1B SMOKERS

10M US SMOKELESS AND SNUS USERS 20M HTP USERS 68M VAPERS

= 10 MILLION PEOPLE
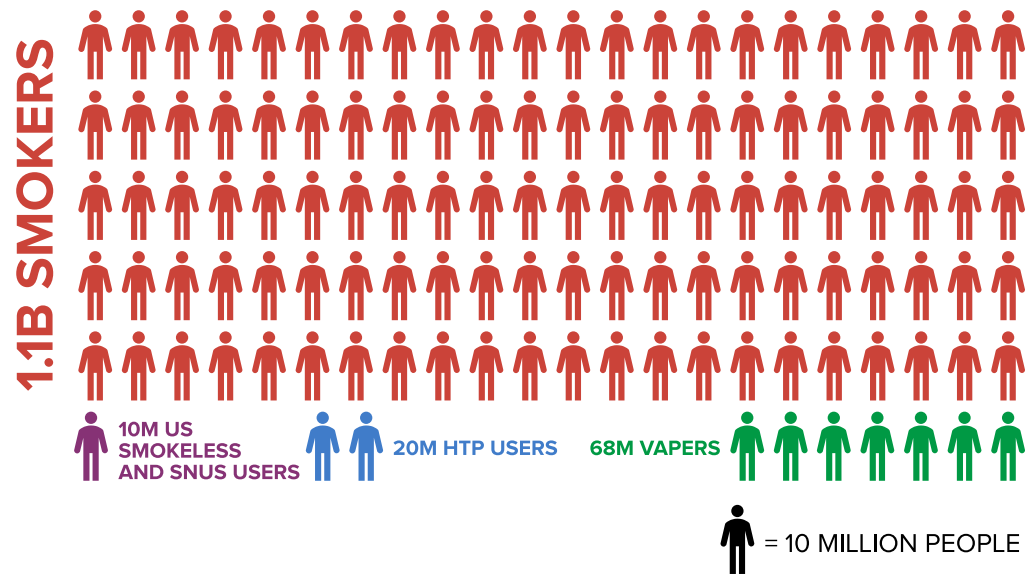
GSTHR 2020.

68 million vaping, 20 million using HTP and 10 million using snus or US smokeless might look like a success, particularly for vaping and HTP which are recent introductions. But is it? A bleak assessment would be not yet. 98 million users of SNP is minuscule compared with continued use of combustible products by 1.1 billion smokers. It only amounts to nine SNP users for every 100 smokers and six vapers for every 100 smokers.

Despite the enthusiasm for safer alternatives, the rate of progress in switching from smoking to SNP is slow. There is an urgent need to scale up tobacco harm reduction. What is needed to make this happen is for products to be:

» Available
Regulation and control should be geared to making these products as readily available as other consumer goods, given that independent and internationally agreed products safety standards are in place. So no outright bans, no flavour bans, no regulation as medicinal products and no exorbitant tobacco-style taxation. Instead, are there ways to incentivise both industry and consumers to switch instead of trying to stub out safer nicotine alternatives?

The rate of progress in switching from smoking to SNP is slow. There is an urgent need to scale up tobacco harm reduction.

» Affordable
This links to the question of consumers' ability, especially in lower and middle-income countries, to afford products. A supportive legislative landscape is required, and other obstacles need to be overcome. For example, mobile phones are ubiquitous across Africa with the capacity to charge them up, so affordable, rechargeable vaping devices must be a possibility, if the will is there from the manufacturers.

» **Appropriate**

Vaping devices might work to replace cigarettes in many countries but won't be appropriate everywhere and with all communities. There are many nicotine consumers, especially in India and South East Asia, who don't smoke conventional cigarettes but instead smoke local varieties or use a range of even more dangerous smokeless tobacco products. It would be hugely beneficial from a public health perspective if these dangerous smokeless products were replaced by far safer snus-type smokeless products.

» **Acceptable**

However, just because more appropriate safer options could be made available does not mean that the target consumer groups would find them acceptable. Public health and commercial marketing strategies would need to account for long-standing social and cultural custom and practice, the nature of the messaging, who is delivering the messages and by what means.

It took around 60 years from the invention of the cigarette rolling machine in 1880 to the end of the Second World War to finally dislodge most other forms of tobacco use in high-income countries.

Can we be encouraged by the rate of change from combustible to non-combustible nicotine delivery? The switch to SNP is encouraging, but to date it is not the public health success that it could be. Sixty years is too long to wait. In that time, many millions of people will die prematurely every year from smoking-related diseases.

Later chapters address the obstacles preventing people switching away from combustibles to SNP. Many more people would have switched without the influence of negative campaigning against THR.

Many more people would have switched to SNP without the negative campaigning against THR.

Chapter 3
Not just the nicotine: consumers speak

Much attention is given to 'expert' views on the use of SNP. Little attention is paid to the millions of ex-smokers who benefit from SNP and who will suffer should legislation grow increasingly prohibitionist.

We interviewed consumers from around the world, hearing how they left smoking behind.

How does the vaper emerge from the smoker?

Smoking per se is not a disease and even if many smokers wish they could quit (or at least wished that they wanted to quit), they do not regard themselves as 'ill' or 'patients' needing 'treatment'.

The social, cultural and psychological dynamics of smoking are complex. In his book *Ashes to Ashes*, Richard Kruger eloquently explores what he calls the 'protean usefulness' of the cigarette, capturing the essence of the pleasure principle. This extract gives a flavour of what smokers are expected to give up and why they find it so hard, especially if they are long time smokers.

> *"The smoker smokes when he feels up or in the dumps when too harassed or overburdened or too unchallenged and idle, when threatened by the crowd at a party or when lonely in a strange place. A smoke is a reward for a job well done, consolation for a job botched. It can fuel the smoker for the intensity of life's daily confrontations yet seem to insulate him from the consuming effects of any given encounter. It defines and punctuates the periods of the smoker's day."*[66]

Older smokers and THR

In Chapter 7, we look at the plight of those we call 'the left behind', including those with mental health and substance use problems or living within minority communities whose smoking rates can be much higher than in the general population. But because the debate about SNP is often focused on the problems that might be faced by young people, the problems of the older smoker are largely ignored.

Because the debate about SNP is focused on the problems that *might* be faced by young people, the problems of the older smoker are largely ignored.

The unspoken narrative appears to be that 'it's too late for them to switch anyway'. However, while surveys of the older vapers and users of other SNP are lacking, there is plenty of anecdotal evidence of older people who have quit smoking for vaping and enjoyed an enhanced quality of life.

It is estimated that people who smoke through their adult life will lose 10-13 years of life compared to non-smokers.[67] But research shows that smokers can significantly reduce the risk of lung cancer if they can stop smoking early enough. Those who quit before they are 40 have a 90 per cent reduced risk of a smoking-related death.[68]

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[66] Kruger, R. (1996). *Ashes to Ashes-America's Hundred-Year Cigarette War, the Public Health, and the Unabashed Triumph of Philip Morris*, NY. Alfred A. Knopf. P. xiii

[67] Doll, R. et al. (2004). Mortality in relation to smoking: 50 years' observations on male British doctors. *BMJ*, 328(7455), 1519. https://doi.org/10.1136/bmj.38142.554479.AE

[68] Jha, P. et al. (2013). 21st-Century Hazards of Smoking and Benefits of Cessation in the United States. *New England Journal of Medicine*, 368(4), 341–350. https://doi.org/10.1056/NEJMsa1211128

It may be harder to convince older smokers to switch because of a smoking habit ingrained over many years. A clutch of surveys reveal the issues; some smokers believe they are 'bulletproof' and will avoid the worst outcomes of smoking;[69] others believe that the risks of smoking have been exaggerated and they can do little to change habits anyway;[70] some believe that it is the nicotine that causes the damage meaning that low nicotine cigarettes are safer.[71]

Vaper from Ireland, aged 73

This convert to vaping had been smoking, for over 50 years, between 15-20 cigarettes a day.

Why did you switch?

Breathing problems mainly. I switched to vaping because my son bought me a vape pen. I continued to do both for about 3 to 4 weeks, but the vape fulfilled what I needed, and I found it very helpful and it was very good when I got onto it. I use an all-in-one device and I have four of them that I switch between, but they are all the same.

I did use the patches at one time before I moved to the vape. I found patches left a taste all day long and I didn't like that. I haven't tried anything else other than the patch.

I have one flavour that I like – hazelnut caramel vanilla flavour. I have tried some of the flavours my son has mixed. I tried the traditional tobacco flavour and I didn't like it at all, so the only one I have liked so far is the hazelnut caramel. My son mixes my favourite flavour but there is also a vape shop not too far away and two local shops sell liquids as well, which means I would be able to find what I need.

I do find a big improvement in my breathing when I'm out walking a lot. My cousin uses the vape and my sister as well. They have seen similar improvements in health and they are a similar age to myself.

"I switched to vaping because my son bought me a vape pen."

The consumer evidence shows much higher uptake of vaping among younger smokers (up to age 44) than among older smokers.[72] They are more likely to be comfortable with the new technology and willing to experiment. For most older smokers, just cracking open the cellophane of the packet, taking out a cigarette and lighting it is so much easier.

Switching in later life does not necessarily undo all the damage of decades of smoking and elderly vapers may still suffer smoking-related diseases, but those who do make the switch usually report a much better quality of life. And as many countries are facing the health and social care costs of an ageing population, public health campaigns should be aimed at older people, and specialist retailers finding ways to attract older smokers into their store. But probably the most effective switching mechanism is for younger smokers who switch to introduce the idea to those older relatives who still smoke.

[69] Borland, R. et al. (2009). Do risk-minimizing beliefs about smoking inhibit quitting? Findings from the International Tobacco Control (ITC) Four-Country Survey. *Preventive Medicine*, 49(2–3), 219–223. https://doi.org/10.1016/j.ypmed.2009.06.015

[70] Kulak, J., & LaValley, S. (2018). Cigarette use and smoking beliefs among older Americans: findings from a nationally representative survey*. *Journal of Addictive Diseases,* 37, 1–9. https://doi.org/10.1080/10550887.2018.1521255

[71] Byron, M. J. et al. (2018). Public misperception that very low nicotine cigarettes are less carcinogenic. *Tobacco Control*, 27(6), 712–714. https://doi.org/10.1136/tobaccocontrol-2017-054124

[72] *Vaping and e-cigarette use by age U.S. 2018.* (2018). Statista. https://www.statista.com/statistics/882611/vaping-and-electronic-cigarette-use-us-by-age/

Consumer stories from around the world

There are two main takeaways from these interviews. Most were smokers from an early age and experienced dramatic health improvements once they switched to SNP. The second is how anti-vaping rhetoric is making it harder for people to access safer products, particularly in the early days of their transition from smoking to safer forms of nicotine consumption. Two of our interviewees in Chile and India were able to benefit from vaping as they were relatively early adopters, before public health officials and politicians got in the way of smokers' health in those countries.

Vaper (image posed by model). Image: shipskyy on Adobe Stock.

Vaper from Ireland

When did you start smoking?

I was smoking from about the age of 20; I started on about 10 a day and then the law changed, and they banned the sale of packets of 10 cigarettes so I started buying 20s and was smoking 20 a day. That went on for 19 or 20 years.

Why did you consider switching to vaping?

"I was one of those people who thought nicotine and vaping was every bit as harmful as smoking."

My father died very young, just turned 56; he had lung cancer and a brain tumour and smoked from the age of 12. So, switching was something I had thought about a few times. I was one of those people who thought nicotine and vaping was every bit as harmful as smoking. But I started asking a few people and then curiosity got the better of me, so I decided to buy one and see how it went. I was just so shocked at how well it worked.

What devices did you try?

I was a dual user for about two weeks, but even in that short space of time I was able to identify a problem: the device wasn't effective enough. So I started looking online and I found a vape shop, there was actually a vape shop in Dublin. I contacted the owner and asked for his advice and he advised me on something else. He talked to me for a long, long time about it.

I would say that within a week or two of getting a better device, a Kangertech Protank 3, that wasn't even expensive – about £30 for the whole thing – I stopped smoking completely. I'm not one of those people that got cravings or relapsed even once or twice, I mean I literally never, ever wanted to go back.

What do you use now?

For convenience I have a little pod system and that's perfectly fine but if I'm at home or relaxing, I would definitely use a box mod because I like the flavour and I make my own juice as well. And I went from 15mg to 1 mg in maybe four months, so it was a massive reduction in nicotine for me.

I've been making my own recipe for a long time because of cost when I switched from the Protank 3 to the sub ohm tank. I got talking to a few guys on forums and started making my own.

Did you see any benefits from vaping?

Just being able to go upstairs and not being out of breath. Your lungs clear out. The sense of smell and taste is crazy. I just don't think you realise how smoking affects your sense of smell and taste. It comes back and you're tasting food that you haven't in 20 years. It's quite a drastic change.

My background was in research and development for an American multi-national so I started researching into the science, because I couldn't believe the change in my health. I was one of those guys who said nicotine is just as harmful.

What do you think of the law on e-cigarettes?

You can't buy the high strength nicotine to make your own. But I still have stuff that I bought pre-TPD [the EU Tobacco Products Directive]. Nicotine keeps for a long time if you store it correctly, so I have loads there.

There are ways to obtain the nicotine but it's not something that I am looking forward to [when my supplies run out] because it is from informal sources, as they say. I know other vapers who struggled after the [EU] TPD law changes because it made it so much more expensive, especially with people who don't know how to handle nicotine, mixing into short fills.[73] It's a bad, bad policy. Very little thought or research went into it because they were arbitrary numbers just plucked out of the sky.

What about friends and family?

Well, there's my mum and I've got an aunt and a cousin that are around about the same age as my mother, late 60s, early 70s, and they're all vaping now and they were all smokers for 45 plus years. My brother is still a smoker, he likes it but also smokes some weed as well. But I really don't know a lot of vapers where I am, it's quite shocking when I go to bigger towns, I'm in quite a rural area [and] it still shocks me the amount of smokers I still see compared to vapers. Media has a big part to play in that.

Vaper from the US

How did you discover vaping?

I started smoking cigarettes when I was 18 – I am 54 now. I smoked until my late 30s and then I had gall bladder surgery. I actually quit then because after surgery you cannot smoke and went smoking cold turkey for two years. I picked up smoking again but not cigarettes; instead I was smoking expensive Davidoff cigarillos.

Last June, I happened to see my food delivery person was vaping. I had already tried JUUL once, I had seen the JUUL commercials about how they helped people switch, but it gave me a horrendous headache. I wasn't looking to quit, just looking to maybe cut down. JUUL didn't work for me because I didn't smoke cigarettes, I smoked

"I stopped smoking completely. I'm not one of those people that got cravings or relapsed even once or twice, I mean I literally never, ever wanted to go back."

"Just being able to go upstairs and not being out of breath. Your lungs clear out. The sense of smell and taste is crazy. You're tasting food that you haven't in 20 years."

"It still shocks me the amount of smokers I still see compared to vapers. Media has a big part to play in that."

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[73] Short-fills are large bottles of e-liquid which are not full to the brim. This allows the vaper to add their own nicotine liquid to work around the EU TPD limits on mg of nicotine per ml of liquid.

cigarillos, so the 'draw' from JUUL was too high for me and I think that's why I was getting this headache. So, I saw this delivery guy and I asked him about it. He had a Smok Novo [pod system]. I did research on Google and YouTube and I watched the documentary put out by Public Health England with the experts and they were explaining how it was safer, so I did a little more research. It quickly evolved from the Smok Novo to an Innokin device. I use what they call free base nicotine e-liquid.

"I watched the documentary put out by Public Health England with the experts and they were explaining how it was safer."

I started with 3 mg but that wasn't cutting it and I was vaping so much extra I became dehydrated. Then I went 6mg and that wasn't cutting it then I watched a YouTube channel dedicated to giving smokers information and advice on vaping and they were saying that sometimes you have to up your nicotine a little bit to satisfy a nicotine craving so I used 12mg and I have been using 12mg since the end of August 2019 and I am quite satisfied.

I started with the fruity flavours, but I found them to be too sweet. I actually did the opposite that most people do, I quickly transitioned away from the fruity flavours and I now I mostly vape tobacco flavours.

What about your health?

I'm a little different from most smokers as I actually didn't have any health problems while I was smoking cigarillos. But I used to exercise a lot and run marathons and half marathons and smoking does damage your lungs, so vaping to me is like I no longer live in fear. Even though I was healthy, every time I coughed I would always spit mucus into a paper towel and look at it to find blood and the first sign of trouble is when you constantly cough and coughing up blood. Since I started vaping, I haven't really coughed a lot.

Did you continue smoking cigarillos while vaping?

"Vaping to me is like I no longer live in fear."

I used both for about two months because I got dehydrated and then I got sick and was back in hospital so I stopped. But if you try to smoke after you have vaped, it tastes really bad, so slowly, without making a conscious decision, I just cut down until finally one morning the first thing
I did was not light up that cigarillo, but reached for the vape.

How easy is it for you to obtain what you need?

When I started in June, I had no idea about all this anti-vaping propaganda that was going on. Shortly after I started vaping, I realised every place is trying to ban this thing. I stepped into a mess. But luckily, when I was researching for the e-liquid on Google, I guess because I did smoke more expensive cigarettes and cigarillos, I was looking for more of a premium artisan e-liquid and then I come across 5 Pawn. It happened that 5 Pawn is next door to where I exercise so very convenient for me to get my e-liquid.

Have you tried other ways to stop smoking?

A long time ago my doctor prescribed Wellbutrin, but the first day I was having heart palpitations, so I stopped it. A couple years later my cardiologist prescribed Chantix. At that time Chantix was not covered by insurance and was quite expensive.

I started reading about side-effects and it mentioned epileptic seizures. My mum said, this is not good especially if you are living by yourself and have a seizure. I tried the patches a couple of times – they also gave me the heart palpitations and then right before I started vaping, I ordered the lozenges from Amazon. I took them twice and they gave me horrible stomach cramps. My family doctor actually said for now go back to smoking as this is not good at all. I even tried hypnosis, but it didn't work, because the hypnotist kept telling me to think of the positive health benefits you are going to get from quitting smoking and I was like well, I run, I'm not overweight, I'm not out of breath, so I couldn't see the benefits, Plus I fell asleep.

Vaper (image posed by model). Image: thodonal on Adobe Stock.

Snus user from Sweden

How long and how regularly were you smoking before you switched to safer nicotine products?

I was smoking about 10 a day for at least 30 years.

Why did you switch to a safer nicotine product?

I was using snus from when I was 18 or 19 years old but back in those days – I am 62 now – people were smoking, drinking and partying so I sort of stuck to both smoking and snus. It was only the loose, tobacco-flavoured snus and I still love the tobacco flavour as well as the salmiak, which is sort of salty liquorice.

Ultimately, I threw away the cigarettes. It was a few days before the Gulf war broke out and I was working in Saudi Arabia as a Chief Financial Officer. My family and I were evacuated with the very last plane and almost missed it. Once I got on the plane, I took the pack of cigarettes and just tore it apart and stuck to snus instead.

"Ultimately, I threw away the cigarettes."

Did you notice any impact on your health from switching to snus and stopping smoking?

Yes definitely, I could run much longer, I didn't cough in the morning and there was no stench indoors. And thankfully in Sweden, snus has been allowed for more than 200 years and it's probably very much the reason why Sweden has the lowest prevalence of smoking in the whole EU as well as the lowest prevalence of smoking mortality.

Have you tried any other safer nicotine products?

Yeah, some years ago, I bought an e-cigarette with a tank and I enjoy vaping on Saturdays along with the snus, and the combination beats smoking cigarettes 100 times anyway.

Do any of your family and friends use safer nicotine products?

I meet many people in my regular life who are using snus and due to my advocacy for tobacco harm reduction, I have contact with thousands of people, men and women from a hundred nations, over 80% of whom are former smokers.

Snus user holding pouches (image posed by model). Image: uskarp2 on Adobe Stock.

Vaper from India

When did you start smoking?

I smoked for over 16 years from the age of about 14.

What impact did that have on your health?

From an early age I went swimming and went to the gym. During school days I was very active in sports, I was the sports captain for my school. Smoking for me was always this childhood dream kind of thing because my entire paternal and maternal side used to smoke, so I was pretty infatuated with it. I got hooked on smoking and as I started smoking more regularly, all the physical activity that I was involved in went down. I was not able to swim as much, not able to play sports or go to the gym. By a decade or so later, I was really in bad shape, chain smoking 40 a day or more. I did not have proper sleep, I used to have a lot of colds, lot of wheezing, I had to keep going to the doctor again and again. That's when I started researching e-cigarettes.

How did you find out about e-cigarettes?

"I was convinced that e-cigarettes could actually work but what was available in India was obsolete, we had old-fashioned stuff, so I went back to smoking."

Our entire group was trying to quit smoking because all of us knew this was really not going our way. In 2013, a friend who used to go to America frequently, brought back these e-cigarettes – the first one where you breathe in and it glows red, but it didn't work out. Then in 2014 I got into vaping for about 6 months, but the devices were no good and the liquid that I started off with was 36 mg nicotine, so it was really not a pleasant experience. But, after 12 years of smoking, I was able to get off cigarettes for 6 long months. That was my first attempt back in 2014.

I was convinced that e-cigarettes could actually work but what was available in India was obsolete, we had old-fashioned stuff, so I went back to smoking. But as soon as I went back to smoking, the old issues started coming back; the colds, the wheezing, the lack of sleep and everything. Eventually, in January 2016, I finally made up my mind that I was going to give up completely. I started connecting with people on Facebook and that is where I landed on the Facebook group consisting of vapers across India. That really helped me and since then I have never gone back to smoking.

By 2016, had access to products improved in India?

Initially it was a bit of a struggle but when I started exploring on Facebook and got into that group, I connected with vapers who were senior to me and they were getting stuff

from China. Once I got in touch with them, there was no looking back. I reached a point where last September I was sponsored by three of the Chinese companies and were promoting them on Instagram as an advocate.

What product do you use?

I use a Rebel single battery device and now I'm more of a hobbyist. I am no longer dependent; I can go an entire week without nicotine or just vaping 3mg. I like any of the sweet flavours.

What difference has quitting cigarettes made to your life?

The first difference was being able to taste everything better. I work in the food industry so for me a refined palette means a lot. The other thing was sense of smell; I can't stand the smell of somebody smoking now, it gives me a headache and I realise how non-smokers feel. I sleep better; I am not a heavy sleeper, but my entire sleep used to be restless. Now I sleep how I used to sleep when I was a teenager before I began smoking. I have gone back to working out and the difference is visible. I am able to do more and my days are longer. I am up and about the moment I wake up.

"Our government has gone the route of no research: they have just banned everything."

How easy is it for you to buy what you need now?

Our government has gone the route of no research: they have just banned everything. For me it is not too difficult to source because I am well connected with the vaping community in India. But for people who are newcomers it is going to be near impossible because nobody is going to sell them anything. I must have converted close to 100 people but if vapes were not banned this number would have gone up and up and more people would have started vaping.

Do your friends and family vape as well?

My maternal uncle switched to vaping and he has been a smoker for 30 years – I was able to convince him off cigarettes.

Are you his supplier then?

No. Initially, anyone I convert to vaping, I make the selection for them depending on their needs. I give them the device in their hands that would suit them best and once they become familiar with that device, I say now you go and explore on your own. So that's what I did with my uncle. I gifted him a device and gave him a bottle of liquid and I told him to try it for a month. In the first month he cut down smoking by half, then he came in the second month and told me, 'Let's go buy another device, I want another device'. Then I got him connected to the seller and now he stocks himself.

"Vaping replaced the action of smoking. Smoking is a ritual – the hand to mouth action. Vaping replicates a lot of that muscle memory."

Before you switched to the vape, had you tried any other products such as a patch or a gum?

Yeah, I have, I tried the gum. I used to smoke while chewing the gum, the gum used to spoil the taste of my mouth and it never went away. I tried the patch once, but it's not as fast as being absorbed in the lung. I think these things are good, but only for people who used to chew tobacco, not for smokers. Vaping replaced the action of smoking. Smoking is a ritual – the hand to mouth action. Vaping replicates a lot of that muscle memory, even if you are just vaping 0 mg. The one thing that vaping does is that it makes you less dependent over time. When I started vaping, I was consuming 200ml a month, now I'm down to 60ml.

Vaper from Chile

When did you start smoking?

I started smoking at 11 until I was 29 and by then I was smoking two packs a day.

And what damage was that doing to your health?

Problems playing sports, running, walking up stairs, lack of smell and taste and my skin and whites of the eyes were yellow.

What prompted you to switch to a safer nicotine product?

I was trying to quit smoking for a long time and tried all the possibilities. I tried patches and I got very nauseous, I tried quitting cold turkey but nothing helped. Only once I was able to quit for like 8 months, but it was like torture each day thinking about cigarettes, especially if I smelled them.

There was no knowledge about e-cigarettes at the time, but in 2009, a friend got one for Christmas and when I took my first puff it was like 'wow, this could help'. But I was not even thinking about quitting, just tried for that one day. The next day, I said I will try keeping going with it, however at 3pm it ran out of battery, so I needed to smoke. That night was the 31st December, New Year's Eve, I said this will be my last cigarette because this thing works, and I never smoked again – no pain, no problems, and it's been 10 years and 2 months.

Do you remember what the first device was? And what do you use now?

I think it was the very first Blu. I used to have lots of different devices – many, many boxes of various products. I have tried all of them. I was part of a group working to get better products in Chile. Some months ago I was using G-class with an RDTA [rebuildable dripping tank atomiser] but I switched back to pods. The pod I like most is the Joytech Exceed grip, but I used to try different things.

For flavours, I go for ice and fruits. We've got some very good stuff here from an alchemist called Blue Metha, the most sold liquid in Chile.

What was the effect on your health? Did you see much improvement?

"I said this will be my last cigarette because this thing works, and I never smoked again – no pain, no problems, and it's been 10 years and 2 months."

It's amazing because most of the benefits you do not know until you quit smoking. The obvious ones are like having a much better physical state, you can walk, you can run, you don't feel tired walking up the stairs, you can do sports and also the colour of my skin changed.

Something that was really amazing to me was that my eyes became whiter. I regained my taste, my smell, even the hair became brighter. I don't know if there is something in tobacco smoke affecting hair, but also the nails became a better colour and more healthy.

When you smoke you are always coughing. When breathing very deeply it felt like a squishy thing in my throat, you can feel something that's not going well. I get less ill from colds during winter. Also in the way you react to other people who smoke. Now, when you go out and you meet a smoker, it's like 'Oh my god, I used to smell this way'.

How easy is it for you to obtain the products you need in Chile?

For me, it is actually very easy because I know the market, but in Chile there is a minister who tried to ban the e-cigarette in 2010. I was in charge of the campaign against him – and we were able to stop him. But then at midnight without anyone knowing, he signed a decree against selling nicotine and only gives power to pharmacies to sell nicotine. So, getting liquids with nicotine is harder for people in Chile. You can find it, but for a newcomer it is difficult because no one will sell to anyone they don't know because they can get in trouble. So, for a normal vaper it is quite easy, but for the ones that are starting, many shops will not sell them nicotine.

Do any of your family or friends use safer nicotine products?

I have switched many people personally; the most difficult person to switch was my mum. She continued to smoke and it was very difficult to get her off the cigarettes. It

was a pity because I was an activist and the person I loved most was still smoking, but with this new pod of Joytech, she was able to quit and she now has her own pod and I am really happy about that. And she is even vaping without nicotine, so that's nice. She has had a better physical state and can do loads of other activities.

An HTP user from Taiwan

When did you start smoking?

I started smoking when I was about 22, I'm 37 now, so that's 15 years. There was nothing in particular affecting my health. But every morning when I would wake up it felt like there was something stuck in my throat and I'd have to spit it out, the colour would be brown or black. After I switched to an HTP that was just gone.

An HTP user (image posed by model). Image: QUALIA studio on Adobe Stock

Did you try any other SNP before trying an HTP?

Vaping and HTP are both illegal in Taiwan, but I did try vaping about three years ago. When vaping kits came out on the market unofficially, I saw advertisements on Facebook, and then I went to a private store and I got this vaping kit and some e-liquid. The experience was quite different from smoking a cigarette, so that didn't last long. I only vaped for maybe a month or two. When I stopped, I just put it in my drawer and never took it out again. I stopped vaping in 2017 and went back to smoking, and then started using an HTP last January.

What was the motivation to try an HTP?

Before I bought it, I'd been to Tokyo and seen this product quite a few times there and seen it on the street and in smoking areas in Taiwan. I thought I should give it a try because it looked like people were changing their ways of smoking to this electric thing. So, why not? I bought it and tried it for a week, while smoking at the same time, then found I couldn't bear the smell of smoking. I didn't really have a reason to quit smoking, I wasn't really trying to quit, I just thought maybe this is a better way. When I have people around me with an HTP, it doesn't smell bad compared to cigarettes and when it cleared up my chest and phlegm, I thought yes, it is better.

So, you were a dual user for a while?

I started to use the HTP on a daily basis and I still smoked cigarettes, but not for long, I think a week. After I finished all my cigarettes, I quit cigarettes. Even now when I'm

drinking with friends and they are smoking I sometimes would borrow one and try to smoke it but that smell and fragrance, I can't take it anymore. The burning smell of cigarettes really stinks.

How easy is it to obtain the products you need?

Because of the law in Taiwan, before COVID, I bought what I needed when I or friends go to Japan. COVID means no one is going out or coming in to the country, so I have to buy from the black market where the prices are 50 per cent higher.

Can you buy the products online?

I think I can order online, and they can deliver, but everything is happening inside the country, not coming from overseas. The people who I buy from have already bought from overseas, then pack the goods in Taiwan and send to me.

Do any of your friends or family use SNP?

My sister smokes but she's not a regular smoker, she smokes when she drinks. I can only think of one friend, my ex-boyfriend. I introduced him to HTP because I think it's healthier, it's cleaner. Now he can't smoke cigarettes anymore even though cigarettes are much cheaper. One pack of 20 cigarettes costs about $3 or $4 but it's $7 or $8 dollars [US] for HTP. So I try to cut down using an HTP because it's so pricey.

Individual health to public health?

As this chapter has shown, consumers have experienced major health benefits from switching from smoking to safer nicotine products. These benefits have been publicly acknowledged by US government officials at the highest levels of public health.

"If you could take every adult smoker and fully switch them to e-cigarettes, that would have a substantial public health impact."
— Dr Scott Gottlieb, FDA
(pictured right)

"If we can get all of those people to completely switch all of their cigarettes for one of those non-combustible products (e-cigs), that would be good for public health."
— Mitch Zeller, FDA
(pictured left)

Dr Gottlieb source: September 25, 2018
http://www.c-span.org/video/?452001-1/fda-commissioner-scott-gottlieb-discusses-cigarettes-public-health-concerns
Mitch Zeller source: May 15, 2014
http://www.help.senate.gov/hearings/progress-and-challenges-the-state-of-tobacco-and-regulation-in-the-us

Chapter 4
Clearing the smoke: safer nicotine products and health

There is much talk in the media about the vaping 'controversy'. Smokers, health professionals, policy makers and legislators are understandably confused by conflicting information from what appear to be opposing but equally credible public health, academic and clinical viewpoints.

It is often said that little is known about vaping and its products. In fact, there has been a massive expansion in the number of scientific publications on vaping. In the six years from 2007-12, there were only 53 publications recorded. This number grew by 459 in 2015; 751 in 2016; 730 in 2017; 1,023 in 2018; 2,017 in 2019; and 793 up to April 2020, totalling 5,773 publications in peer-reviewed scientific journals. In the seven years from 2013 to 2020, the total covering vaping, HTP products and snus jumped to 6,309.[74]

There are fewer publications on other SNP. There were only three publications on HTP in 2015; 26 in 2016; 31 in 2017; 90 in 2018; 95 in 2019; and 48 in 2020. In total there were 293 publications on HTP between January 2015 and April 2020.

On snus there were 27 publications in 2015; 61 in 2016; 47 in 2017; 42 in 2018; 53 in 2019 and 13 in 2020. In total, 243 publications on snus from January 2015 to April 2020.

By mid-2020 –

6,309

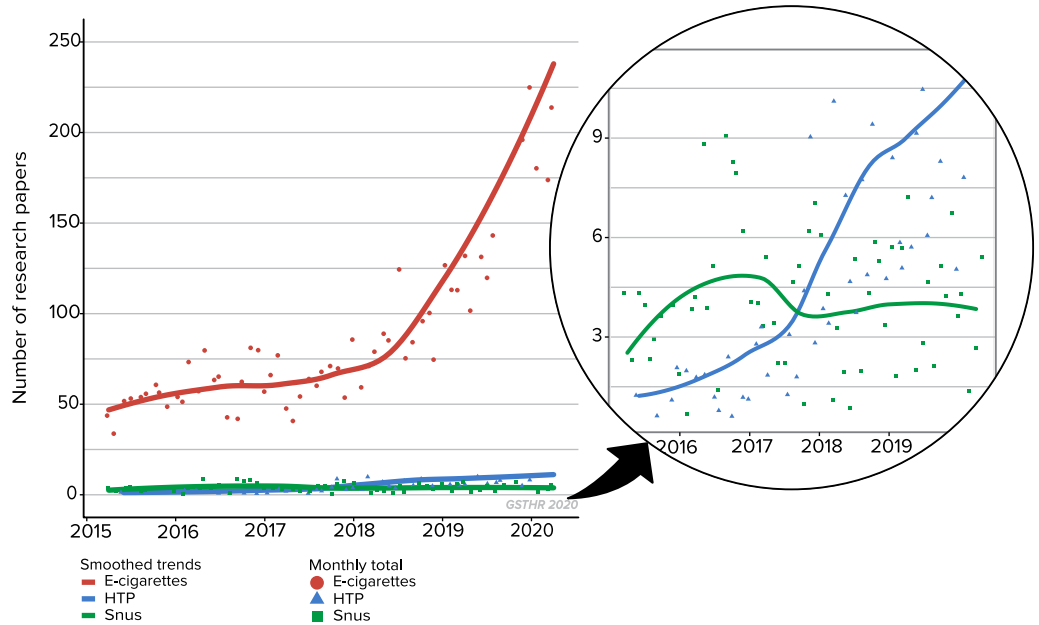**scientific articles had been published on SNP.**
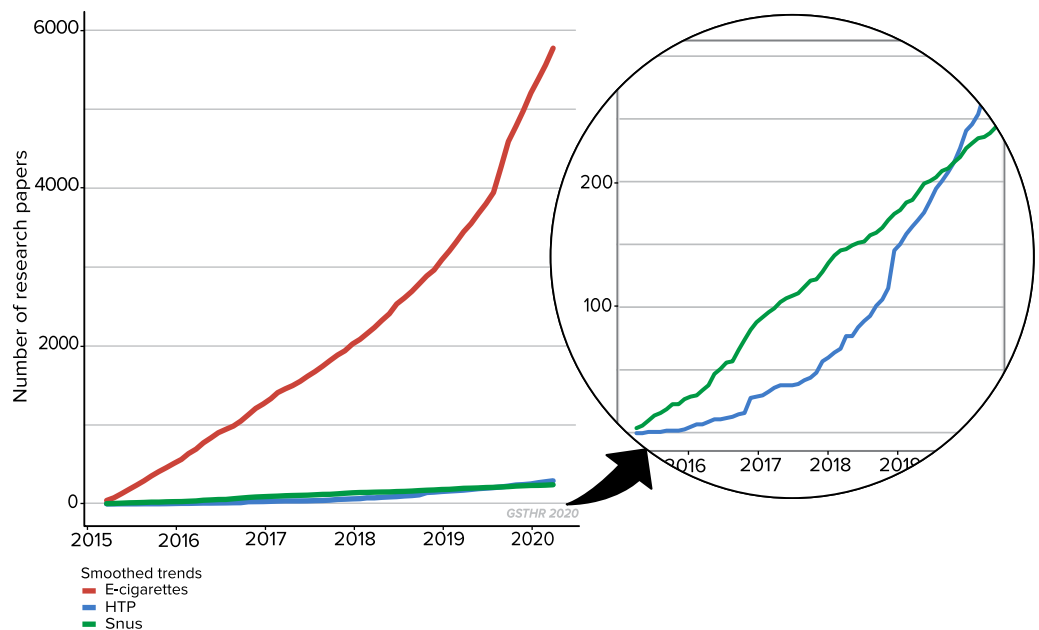

Image: vkotenko2012 on Adobe Stock

But more science does not always mean better science or better science communication. Poorly formulated and designed research, over-cooked announcements of research results,

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[74] Signals Analytics, Inc. Accessed 17 June 2020.

Monthly number of research papers

GSTHR 2020

Smoothed trends
- E-cigarettes
- HTP
- Snus

Monthly total
- E-cigarettes
- HTP
- Snus

Cumulative number of research papers

GSTHR 2020

Smoothed trends
- E-cigarettes
- HTP
- Snus

Data source: Signals Analytics, Inc. (Jun 2020)

over-hyped university press releases and an uncritical media with an appetite for bad news stories create confusion among the general public, smokers and users of SNP and health professionals. Taking a balanced view of any issue is not a question of giving equal weight to both sides but making a calculation based on the most robust and credible evidence.

There is also a wider issue of what might be termed 'nicotine illiteracy' which goes beyond anti-THR rhetoric: a belief among health professionals and the public that nicotine is carcinogenic.[75,76,77]

[75] Moysidou, A. et al. (2016). Knowledge and Perceptions about Nicotine, Nicotine Replacement Therapies and Electronic Cigarettes among Healthcare Professionals in Greece. *International Journal of Environmental Research and Public Health*, 13(5). https://doi.org/10.3390/ijerph13050514

[76] Ratschen, E. et al. (2009). Tobacco dependence, treatment and smoke-free policies: a survey of mental health professionals' knowledge and attitudes. *General Hospital Psychiatry*, 31(6), 576–582. https://doi.org/10.1016/j.genhosppsych.2009.08.003

[77] Ramesh Patwardhan, S., & Murphy, M. A. (2013). Survey of GPs' understanding of tobacco and nicotine products. *Drugs and Alcohol Today*, 13(2), 119–150. https://doi.org/10.1108/DAT-02-2013-0010

Key points about SNP and health

1. There is no such thing as absolute safety. Medicines, whether prescribed or bought over the counter, come with lists of possible side effects and risks.
2. The 'dose makes the poison'. Much depends on the dosage of any substance or the route of delivery into the body. For example, a drug which is injected will reach the brain far quicker than one which is swallowed.
3. Vaping and HTP emit substantially fewer toxins than conventional combustible cigarettes, meaning that the potential health risks from smoking are dramatically reduced by switching away from cigarettes. Safer smokeless products, like snus and US smokeless, produce no emissions.
4. Most studies only consider the potential absolute health risks of these products – and incidentally find little evidence – rather than looking at the *relative* risk compared to smoking cigarettes. Relative risk studies focus on reductions in exposures. This doesn't mean there is no risk, but underlines the key point that the spotlight is on tobacco harm *reduction* not *elimination*.
5. Someone who has been smoking for decades can enjoy an enhanced quality of life if they switch away from smoking. However, switching or even quitting altogether does not necessarily mean they will not suffer a smoking-related disease at some point, because of the damage already done.
6. In relation to long-term effects of vaping products – many people have been vaping for over a decade from all over the world without evidence of ill effects directly and exclusively related to vaping. Just because we don't know everything, does not mean we don't know anything.
7. No new evidence has appeared since our last report to challenge the best available evidence that using vaping devices, HTP and snus is significantly safer than smoking.

No new evidence has appeared since our last report to challenge the best available evidence that using vaping devices, HTP and snus is significantly safer than smoking.

In the context of tobacco harm reduction – what does 'safer' mean?

When a smoker draws on a cigarette, the temperature at the tip rises from about 700 degrees centigrade to 900 degrees – enough to melt metals including aluminium and lead – releasing some 7,000 detected compounds, of which at least 70 are carcinogens. Tobacco is also combusted in cigars, cigarillos and pipes. It is these toxins which create (once water and nicotine are filtered out of the smoke) tar, which is one of the main factors contributing to cancer and other cardiovascular and respiratory diseases. No other way of consuming nicotine comes close to the dangers posed by smoking, as the chart below shows.

No other way of consuming nicotine comes close to the dangers posed by smoking.

Image: Feng Yu on Adobe Stock

Continuum of risk for nicotine containing products

> *"Vaping poses only a small fraction of the risk of smoking and switching completely [...] conveys substantial health benefits."* – Public Health England, 2020
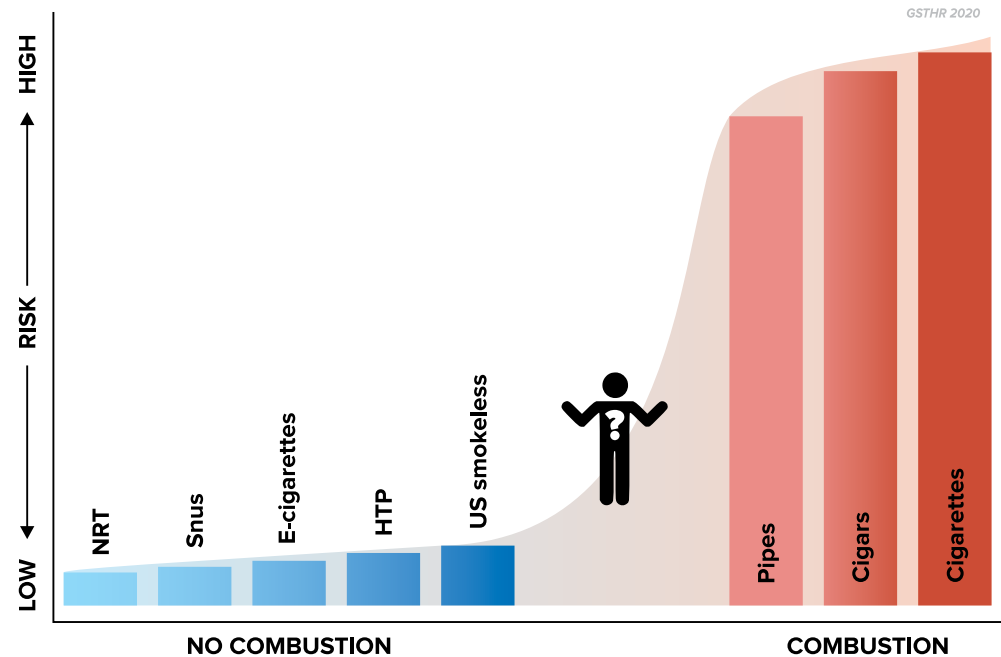
Regarding **vaping devices** and based on a comprehensive evidence review, Public Health England (PHE) confirmed in its 2020 report their earlier conclusion that:

> *"Vaping poses only a small fraction of the risk of smoking and switching completely from smoking to vaping conveys substantial health benefits over continued smoking. Based on current knowledge stating that vaping is at least 95% less harmful than smoking remains a good way to communicate the large difference in relative risk so that more smokers are encouraged to make the switch from smoking to vaping."[78]*

With **HTP**, the situation is slightly different because tobacco is involved and is heated (at different temperatures depending on the device) although never above 350°C, and so below the combustion temperature of cigarettes. It is crucial to demonstrate that no combustion occurs with HTP. This can be done by showing that the devices work in the absence of oxygen. An independent assessment, conducted for New Zealand's Ministry of Health, confirmed that no combustion occurs in the heated tobacco product IQOS when used as intended.[79]

PHE and the UK Committee on Toxicity, Carcinogenicity and Mutagenicity of Chemicals in Food, Consumer Products and the Environment considered the available evidence in 2017.[80] The UK Committee on Toxicity (COT) highlighted significant reductions in levels of harmful and potentially harmful constituents (HPHCs) in the aerosol of HTP compared to cigarette smoke and stated that "[t]here would likely be a reduction in risk for conventional smokers deciding to use heat-not-burn tobacco products instead of smoking cigarettes."[81] COT added that "[a] reduction in risk would also be experienced by bystanders where smokers switch to heat-not-burn tobacco products".[82]

[78] McNeill, A. et al. (2020). *Vaping in England: 2020 evidence update summary* (Research and Analysis). Public Health England (PHE). https://www.gov.uk/government/publications/vaping-in-england-evidence-update-march-2020/vaping-in-england-2020-evidence-update-summary

[79] Ministry of Health v Philip Morris (New Zealand) Limited [2018] NZDC 4478. Available at http://www.districtcourts.govt.nz/assets/unsecure/2018-03-27/2018-NZDC-4478-MOH-v-Morris.pdf

[80] *Toxicological evaluation of novel heat-not-burn tobacco products – non-technical summary.* (2017). UK Committee on Toxicity. https://cot.food.gov.uk/sites/default/files/heat_not_burn_tobacco_summary.pdf

[81] *Statement on heat not burn tobacco products.* (2017). UK Committee on Toxicity. https://cot.food.gov.uk/sites/default/files/heat_not_burn_tobacco_statement.pdf

[82] *Statement on heat not burn tobacco products.* (2017). UK Committee on Toxicity. https://cot.food.gov.uk/sites/default/files/heat_not_burn_tobacco_statement.pdf

Most of the scientific and clinical literature on HTP has been provided by the industry. However, the body of independent research on these products is growing. In 2018, PHE reviewed 20 extant studies (12 of which were the product of tobacco company research) and reiterated these points based on the available evidence and noted the potential of HTP: "Compared with cigarette smoke, heated tobacco products are likely to expose users and bystanders to lower levels of particulate matter and harmful and potentially harmful compounds. The extent of the reduction found varies between studies. [...] The available evidence suggests that heated tobacco products may be considerably less harmful than tobacco cigarettes and more harmful than e-cigarettes."[83] Independent analytical chemistry studies on HTP have confirmed manufacturers' findings showing that HTP products generate much lower levels of harmful constituents compared to tobacco cigarettes.[84,85,86] A review of studies of likely daily exposure indicated that cancer risk from HTP is between one and 10 per cent

"Based on current knowledge stating that vaping is at least 95% less harmful than smoking remains a good way to communicate the large difference in relative risk so that more smokers are encouraged to make the switch from smoking to vaping."
– Public Health England

Image: librakv on Adobe Stock

83　McNeill A, Brose LS, Calder R, Bauld L & Robson D. (2018). *Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England.* (p. 243). Public Health England. https://assets.publishing.service. gov.uk/government/uploads/system/uploads/attachment_data/file/684963/Evidence_review_of_e-cigarettes_and_ heated_tobacco_products_2018.pdf

84　Bekki, K. et al. (2017). Comparison of Chemicals in Mainstream Smoke in Heat-not-burn Tobacco and Combustion Cigarettes. *Journal of UOEH*, 39(3), 201–207. https://doi.org/10.7888/juoeh.39.201

85　Li, X. et al. (2019). Chemical Analysis and Simulated Pyrolysis of Tobacco Heating System 2.2 Compared to Conventional Cigarettes. *Nicotine & Tobacco Research: Official Journal of the Society for Research on Nicotine and Tobacco*, 21(1), 111–118. https://doi.org/10.1093/ntr/nty005

86　Mallock, N. et al. (2018). Levels of selected analytes in the emissions of "heat not burn" tobacco products that are relevant to assess human health risks. *Archives of Toxicology*, 92(6), 2145–2149. https://doi.org/10.1007/s00204-018-2215-y

that of cigarettes.[87] A comprehensive independent review looked at the evidence from 31 studies, including eight that were not industry-based, but all of which were peer-reviewed, concluding that devices delivered up to 75 per cent fewer harmful toxins and overall that HTP "expose users and bystanders to substantially fewer harmful and potentially harmful compounds than smoking cigarettes".[88]

The evidence on smokeless products

US smokeless[89]

The risks are so small that even large epidemiologic studies with hundreds of thousands of users cannot provide indisputable evidence that smokeless tobacco (ST) causes any specific disease.

It has been known for almost three decades that those who avoid smoking cigarettes – known as chewers and dippers and those who use snus – eliminate about 98 per cent of the risks associated with smoking.[90] The risks are so small that even large epidemiologic studies with hundreds of thousands of users cannot provide indisputable evidence that smokeless tobacco (ST) causes any specific disease.[91] With risks that small, it is not possible to prove that one kind of dip, chew or snus is safer than the other[92].

Decades of scientific studies document that ST use is vastly safer than smoking with respect to cancer,[93] heart attack and strokes[94] and many other diseases. In 2002, a report by the Royal College of Physicians stated, "As a way of using nicotine, the consumption of non-combustible [smokeless] tobacco is in the order of 10–1,000 times less hazardous than smoking, depending on the product."[95] In 2008, the American Association of Public Health Physicians became the first medical organisation in the US to formally adopt a policy of "encouraging and enabling smokers to reduce their risk of tobacco-related illness and death by switching to less hazardous ST products."[96]

The Global Burden of Diseases, Injuries and Risk Factor Study provides a comprehensive assessment of risk factor exposure and attributable burden of disease. For example, the 2016 study states:

> *"for the first time in the GBD study, we estimated exposure to and burden attributable to smokeless tobacco... RR [Reduced Risk] estimates were derived from prospective cohort studies and case-control studies... Based on available evidence, for chewing tobacco, RRs were significantly higher than one for oral cancer and oesophageal cancer, while for snus or snuff we did not find sufficient evidence of an RR greater than one for any health outcome".*[97]

[87] Ed Stephens. (2018, June 16). *Modelling the effects of user exposure to harmful emissions across the spectrum of nicotine delivery*. Global Forum on Nicotine, Warsaw. https://gfn.net.co/downloads/2018/EdStephens.pdf

[88] Simonavicius, E. et al. (2019). Heat-not-burn tobacco products: a systematic literature review. *Tobacco Control*, 28(5), 582–594. https://doi.org/10.1136/tobaccocontrol-2018-054419

[89] Text and references supplied by Brad Rodu, Professor of Medicine at the University of Louisville, Kentucky.

[90] Rodu, B. (2014). *For Smokers Only: How Smokeless Tobacco Can Save Your Life*. Sumner Books.

[91] Fisher, M. T. et al. (2019). Smokeless tobacco mortality risks: an analysis of two contemporary nationally representative longitudinal mortality studies. *Harm Reduction Journal*, 16(1), 27. https://doi.org/10.1186/s12954-019-0294-6

[92] Rodu, B. (2016, July 20). Tobacco Truth: Is Snus Safer Than Dip or Chew? Health Effects of All Are Close to Zero. *Tobacco Truth*. https://rodutobaccotruth.blogspot.com/2016/07/is-snus-safer-than-dip-or-chewhealth.html

[93] Rodu, B. (2009, August 13). Tobacco Truth: Cancer Risks from Smokeless Tobacco Use: Next To Nil. *Tobacco Truth*. https://rodutobaccotruth.blogspot.com/2009/08/cancer-risks-from-smokeless-tobacco-use.html

[94] Rodu, B. (2009, August 19). Tobacco Truth: Heart Attack and Stroke Risks from Smokeless Tobacco Use: Next to Nil. *Tobacco Truth*. https://rodutobaccotruth.blogspot.com/2009/08/heart-attack-and-stroke-risks-from.html

[95] Royal College of Physicians of London Tobacco Advisory Group. (2002). *Protecting Smokers, Saving Lives: The Case for a Tobacco and Nicotine Regulatory Authority*. Royal College of Physicians.

[96] Nitzkin JL, Rodu B. (2008). *The case for harm reduction for control of tobacco-related illness and death. Resolution and White Paper.* American Association of Public Health Physicians; Wayback Machine. https://web.archive.org/web/20100510170828/http://www.aaphp.org/special/joelstobac/20081026HarmReductionResolutionAsPassedl.pdf

[97] Gakidou, E. et al. (2017). Global, regional, and national comparative risk assessment of 84 behavioural, environmental and occupational risks or clusters of risks, 1990–2016: a systematic analysis for the Global Burden of Disease Study 2016. *The Lancet*, 390(10100), 1345–1422. https://doi.org/10.1016/S0140-6736(17)32366-8

Snus

The use of snus in Sweden provides a real-world proof of concept for THR using SNP and one that could potentially deliver significant benefits in those regions where more dangerous smokeless products have become culturally embedded.[98]

Image: uskarp2 on Adobe Stock

Snus use in Sweden is high compared to smoking, enabling the country to enjoy the lowest rate of smoking-related mortality in Europe and half the average EU rate for smoking-related disease. The low levels of smoking mean there are low levels of respiratory disease linked with inhalation. Additionally, the epidemiological evidence is that snus is not associated with diabetes, oral and pancreatic cancers, or cardiovascular disease.[99,100,101,102,103,104]

In its 2008 investigation, the EU Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) reported several conclusions about the health effects of ST and snus. Significantly, it found that complete substitution of ST for tobacco smoking would ultimately prevent nearly all deaths from respiratory disease currently caused by smoking and reduce the cardiovascular mortality that currently arises from smoking by at least 50%. They also concluded that there was no obvious gateway effect from snus to cigarettes among young Swedish people.[105]

[An EU scientific committee found that] complete substitution of ST for tobacco smoking would ultimately prevent nearly all deaths from respiratory disease currently caused by smoking.

98   While fewer women than men smoke cigarettes, in parts of India, for example, there are high rates of head and neck cancer among low income women using smokeless tobacco products.
99   Carlsson, S. et al. (2017). Smokeless tobacco (snus) is associated with an increased risk of type 2 diabetes: results from five pooled cohorts. *Journal of Internal Medicine*, 281(4), 398–406. https://doi.org/10.1111/joim.12592
100 Rasouli, B. et al. (2017). Use of Swedish smokeless tobacco (snus) and the risk of Type 2 diabetes and latent autoimmune diabetes of adulthood (LADA). *Diabetic Medicine: A Journal of the British Diabetic Association*, 34(4), 514–521. https://doi.org/10.1111/dme.13179
101 Lee, P. N. (2011). Summary of the epidemiological evidence relating snus to health. *Regulatory Toxicology and Pharmacology: RTP*, 59(2), 197–214. https://doi.org/10.1016/j.yrtph.2010.12.002
102 Araghi, M. et al. (2017). Use of moist oral snuff (snus) and pancreatic cancer: Pooled analysis of nine prospective observational studies. *International Journal of Cancer*, 141(4), 687–693. https://doi.org/10.1002/ijc.30773
103 Hansson, J. et al. (2009). Use of snus and risk for cardiovascular disease: results from the Swedish Twin Registry. *Journal of Internal Medicine*, 265(6), 717–724. https://doi.org/10.1111/j.1365-2796.2009.02081.x
104 WHO Study Group on Tobacco Product Regulation. (2010). *Report on the Scientific Basis of Tobacco Product Regulation* (No. 955). WHO. https://www.who.int/tobacco/global_interaction/tobreg/publications/tsr_955/en/
105 *Scientific Committee on Emerging and Newly Identified Health Risks. Health effects of smokeless tobacco products. Health and Consumer Protection Directorate, European Commission, 2008*. Available at ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_013.pdf

US lung injuries and deaths: mistakes, miscommunication and misinformation[106]

A key health issue that has arisen since our 2018 report was the outbreak of serious lung injuries and deaths in the US.

From around March-April 2019, cases of lung disease (cough, shortness of breath, difficulty breathing, fatigue and vomiting) emerged in Illinois and Wisconsin with a rapid increase in reporting occurring in August and September across the US. The first death occurred on 23 August 2019. As of March 2020, just under 3,000 people had been hospitalised with around 70 deaths. There have been no confirmed deaths outside the US.

Early official public health reporting called the outbreak 'e-cigarette' or vaping product associated lung injury or EVALI, leading many to believe that conventional nicotine vaping products were responsible. It soon became clear that a more appropriate name would have been vitamin E-related lung injury or VITERLI because the substance doing the damage was vitamin E acetate. This oil-based substance has never been detected in ordinary nicotine e-liquid, which is water-based.

People affected by VITERLI were inhaling vaporised cannabis (THC) oil to which vitamin E acetate had been added to give the appearance in texture and colour of a high-quality oil in illicitly manufactured THC cartridges. Some of those hospitalised initially claimed they had been vaping nicotine liquid, but subsequent questioning and testing found substantial under-reporting of marijuana, likely due in part to use still being illegal in many parts of the US.[107] The cannabis website Leafly charted the causes of the outbreak and first exposed the multi-billion dollar industry producing and selling illicit THC oil and fake THC vaping devices and associated accessories.[108,109,110]

In August 2019, a Los Angeles wholesalers advertised vape hardware, terpenes, and diluent thickeners – 'honey cut' – associated with VITERLI.
Credit: David Downs Leafly

[106] See also O'Leary, R., & Polosa, R. (2020). Tobacco harm reduction in the 21st century. *Drugs and Alcohol Today*, ahead-of-print(ahead-of-print). https://doi.org/10.1108/DAT-02-2020-0007

[107] Blount, B. C. et al. (2019). Vitamin E Acetate in Bronchoalveolar-Lavage Fluid Associated with EVALI. *New England Journal of Medicine*, 382(8), 697–705. https://doi.org/10.1056/NEJMoa1916433

[108] Downs, D. et al. (2019, September 24). Journey of a Tainted Vape Cartridge: from China's labs to your lungs. A Leafly Investigation. *Leafly*. https://www.leafly.com/news/politics/vape-pen-injury-supply-chain-investigation-leafly

[109] Downs, D. (2019, September 11). Vape Pen Lung Disease: Vitamin E Oil Explained. *Leafly*. https://www.leafly.com/news/health/vape-pen-lung-disease-vitamin-e-oil-explained

[110] Note that devices produced for vaping nicotine e-liquid are not suitable for vaping THC. The reason the products are incompatible is that e-liquid atomisers are designed for the relatively thin PG/VG e-liquid mixture, and cannabis oil atomizers are specifically made to vaporise ultra-thick THC oil. The coils and wicks of one will not handle the substance meant for use in the other.

The Centre for Disease Control (CDC) VITERLI timeline[111]

To the astonishment of many vapers and THR professionals, in 2020 the CDC lung injury team was nominated for a Service to America award for its response to the outbreak. By contrast, many critics thought that the CDC took advantage of its existing opposition to vaping to spread fear and misinformation. Media reporting in the US and around the world "contributed to regulatory over-reactions to nicotine vaping by the public health community".[112] This misreporting continued even after the CDC finally revealed that the vaping of illicit THC was causing the deaths and injuries.[113]

- **25th July**: Wisconsin Department of Health Services sends a memo to healthcare providers concerning severe pulmonary disease among adolescents who reported vaping and other 'inhalant drug use'. Types of products used were unknown and patient interviews ongoing.

- **12th August**: California Department of Public Health issues an alert to the effect that "reported common exposure among these patients is that they have been vaping cannabis or cannabidiol (CBD) oils. At this time, no infectious cause has been identified."

- **23rd August**: Brian King of the CDC Office on Smoking and Health tells reporters:

  "...there's a variety of harmful ingredients identified [in nicotine vaping products], including things like ultrafine particulates, heavy metals like lead, and cancer-causing chemicals. And flavoring used in e-cigarettes to give it a buttery flavor, diacetyl, and it's been related to severe respiratory illness. That being said, we haven't specifically linked any of those specific ingredients to the current cases, but we know that e-cigarette aerosol is not harmless."

  Meanwhile there had been 193 acute lung injury cases and 1 death. In all cases, illicit THC oil cartridges had been identified as the specific product most likely responsible.

- **28th August**: USA Today reports: "People are vaping THC. Lung injuries being reported nationwide. Why is the CDC staying quiet?"

- **5th September**: New York Times reports that, "The state said that the Vitamin E compound was found in tests of cannabis products, but not in the nicotine-based products it tested, a finding consistent with reports from doctors that many illnesses have been linked to people using a vaping device for marijuana."

- **6th September**: Despite the growing body of evidence about the true cause of the outbreak, the CDC tell the Washington Post that when it came to clinical tests, "We don't know what we're looking for".

- **4th October**: Tentative FDA warning not to vape THC.

- **25th October**: Despite 33 deaths directly linked to vaping THC, the CDC tell reporters, "We recommend that you do not use e-cigarette, or vaping, products that contain THC. And since the specific compounds or ingredients causing lung injury are not yet known, the only way to be sure that you are not at risk is to consider refraining from use of all e-cigarette, or vaping, products while our investigation continues."

- **8th November**: New York Times reports that the CDC has finally linked the illnesses and deaths to vitamin E. However, allegations against nicotine vaping products continue: "Nicotine has not been exonerated... Some patients say they vaped only nicotine, and state health officials consider some of those reports reliable".

- **25th February**: CDC says that "... Adults using nicotine-containing e-cigarette, or vaping, products as an alternative to cigarettes should not go back to smoking... If they choose to use e-cigarettes as an alternative to cigarettes, they should completely switch from cigarettes to e-cigarettes and not partake in an extended period of dual use of both products that delays quitting smoking completely...".[114]

[111] Jim McDonald. (2020, May 8). A Look Back at CDC's Award-Nominated "EVALI" Response. *Vaping360*. https://vaping360.com/vape-news/90032/a-look-back-at-cdcs-award-nominated-evali-response/

[112] Hall, W. et al. (2020). Lessons from the public health responses to the US outbreak of vaping-related lung injury. *Addiction (Abingdon, England)*. https://doi.org/10.1111/add.15108

[113] Gartner, C. et al. (2020). Miscommunication about the causes of the US outbreak of lung diseases in vapers by public health authorities and the media. *Drug and Alcohol Review*, 39(1), 3–6. https://doi.org/10.1111/dar.13024

[114] CDC's Office on Smoking and Health. (2020, February 25). *Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products*. Centers for Disease Control and Prevention. https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html

Writing for Leafly, David Downs and colleagues estimated that 78 per cent of the US THC vaping business is outside any regulation or control – starkly revealed when the authors had some residual oil from one VITERLI victim tested by SC Labs, an accredited California- based facility specialising in cannabis product testing. The lab not only found vitamin E, but also lead and pesticides in "insane concentrations", to quote SC Lab President, Josh Wurzer.

How does vitamin E specifically cause damage? Vitamin E acetate disrupts the function of the lungs' fluid lining, impeding oxygen transfer, and triggering a progressive and severe immune reaction. Some reports indicate a person's lungs can begin to lose function as quickly as a week after exposure to THC oil heavily cut with vitamin E acetate.

"When you inhale this fatty substance, it sort of acts like a soap," said Wurzer. "When it gets in your lungs, it breaks up all the surface chemistry that's happening with your lungs and really interferes with the exchange of oxygen into your bloodstream."

Local public health authorities identified the root cause of the problem from the outset. This did not prevent US anti-THR activists, federal agencies and politicians using the VITERLI outbreak as a way to further their agenda and call for bans. A lesson to be learned is that banning products already in wide circulation allows a criminal market in unregulated and potentially dangerous products to step in.

> **[The evidence] did not prevent US anti-THR activists, federal agencies and politicians using the VITERLI outbreak as a way to further their agenda and call for bans.**

Is there evidence that vaping increases the risk of lung and heart disease?

Health concerns about nicotine vaping products focus on the effects of vapour constituent deposits in the mouth, upper airway and lungs and the overall effects on bodily functions of vapour inhalation.[115] These constituents include nicotine, propylene glycol, glycerine and flavours.

Nicotine is a psychoactive substance, but at commonly used dose levels, short-term nicotine use does not result in clinically significant harm[116] while the long-term adverse effects are also likely to be minimal.[117,118]

According to the **International** Agency for Research on Cancer (IARC) nicotine is not a carcinogen[119] and a US Surgeon General's report concluded nicotine does not contribute to respiratory diseases.[120]

Tobacco smoke and vapour follow the same pathway into the mouth and upper airway, through the gastrointestinal tract and are then excreted. The deposit and absorption of smoke-derived carcinogens increase the cancer risk impacting on various organs but, given the very low level of potential carcinogens in vapour, the risk – either relative or absolute – is low.

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[115] Polosa, R. et al. (2019). The effect of e-cigarette aerosol emissions on respiratory health: a narrative review. *Expert Review of Respiratory Medicine*, 13(9), 899–915. https://doi.org/10.1080/17476348.2019.1649146

[116] RCP policy: public health and health inequality. (2016). *Nicotine without smoke: Tobacco harm reduction*. Royal College of Physicians. https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction, p. 58

[117] *Smoking: harm reduction* (Guidance No. PH45; Public Health Guideline). (2013). National Institute for Health and Care Excellence (NICE). https://www.nice.org.uk/Guidance/PH45

[118] Mayer, B. (2014). How much nicotine kills a human? Tracing back the generally accepted lethal dose to dubious self-experiments in the nineteenth century. Archives of Toxicology, 88(1), 5–7. https://doi.org/10.1007/s00204-013-1127-0

[119] IARC. (2004). *Tobacco Smoke and Involuntary Smoking*. World Health Organisation International Agency for Research on Cancer. https://publications.iarc.fr/Book-And-Report-Series/Iarc-Monographs-On-The-Identification-Of-Carcinogenic-Hazards-To-Humans/Tobacco-Smoke-And-Involuntary-Smoking-2004

[120] National Center for Chronic Disease Prevention and Health Promotion (US) Office on Smoking and Health. (2014). *The Health Consequences of Smoking – 50 Years of Progress: A Report of the Surgeon General*. Centers for Disease Control and Prevention (US). http://www.ncbi.nlm.nih.gov/books/NBK179276/

There is the possibility of vapour-induced lung irritation and the attendant increased risk of adverse respiratory impact in people with hypersensitivities to certain chemicals. However, many smokers who switch report improvements in lung function.[121,122] A study by Jacob George and colleagues concluded that consumers of vaping products, especially women, "demonstrate significant improvement in vascular health within 1 month of switching [from smoking cigarettes to vaping]".[123]

Regarding propylene glycol in vaping products, apart from possible minor irritation, there are no other known harmful effects, while animal studies have failed to demonstrate harmful effects on the lungs of inhaling glycerine. Lower incidence of airway infections of smokers who had switched to vaping products has been reported.[124,125]

A widely-cited study claimed to have detected an excessive presence of metals in vapour.[126] However, the authors evaluated the exposure to metals in vapour in terms of total air breathed on a daily basis, when vapers are only exposed while vaping, which is typically 150–200 four- to six-second puffs per day, that is, an exposure of 12–16 minutes per day.[127]

Concerns have been expressed about the safety of some ingredients used in creating flavours. These are industry standard ingredients for oral consumption in food, but can be risky when inhaled, including diacetyl and acetyl propionyl (used in sweet/buttery flavours), although there are other safer compounds producing a buttery flavour.[128] There has been much media coverage of a condition known as 'popcorn lung' (bronchiolitis obliterans), suffered by employees working in popcorn factories who have been exposed to high levels of this compound.

The symptoms, such as coughing, shortness of breath and wheezing, might be indistinguishable from the effects of long-term smoking in a vape consumer who had switched, although exposure levels would be several orders of magnitude lower than a factory environment. This respiratory condition has never been reported in vapers. Even so, manufacturers are now avoiding flavours that contain diacetyl: in the EU it is now banned. There has been some debate about cinnamon flavours (which cannot be reproduced using anything but cinnamaldehyde), but evidence again suggests this is primarily an occupational health issue in the factory environment where large quantities are used.

Other chemical components in vaping liquids are generated when the liquid is heated, including formaldehyde and acrolein, while the device and the device elements can also release aerosolised particles of metal, ceramic and rubber when heated. Exposure

121 Polosa, R. et al. (2014). Effect of Smoking Abstinence and Reduction in Asthmatic Smokers Switching to Electronic Cigarettes: Evidence for Harm Reversal. *International Journal of Environmental Research and Public Health*, 11(5), 4965–4977. https://doi.org/10.3390/ijerph110504965

122 Polosa, R. et al. (2018). Health effects in COPD smokers who switch to electronic cigarettes: a retrospective-prospective 3-year follow-up. *International Journal of Chronic Obstructive Pulmonary Disease*, 13, 2533–2542. https://doi.org/10.2147/COPD.S161138

123 George, J. et al. (2019). Cardiovascular Effects of Switching From Tobacco Cigarettes to Electronic Cigarettes. *Journal of the American College of Cardiology*, 74(25), 3112–3120. https://doi.org/10.1016/j.jacc.2019.09.067

124 Polosa, R. et al. (2016). Evidence for harm reduction in COPD smokers who switch to electronic cigarettes. *Respiratory Research*, 17(1), 166. https://doi.org/10.1186/s12931-016-0481-x

125 Miler, J. A., & Mayer, B. (2016). Changes in the Frequency of Airway Infections in Smokers Who Switched To Vaping: Results of an Online Survey. *Journal of Addiction Research & Therapy*, 7. https://doi.org/10.4172/2155-6105.1000290

126 Olmedo Pablo et al. (n.d.). Metal Concentrations in e-Cigarette Liquid and Aerosol Samples: The Contribution of Metallic Coils. *Environmental Health Perspectives*, 126(2), 027010. https://doi.org/10.1289/EHP2175

127 Farsalinos, K. E., & Rodu, B. (2018). Metal emissions from e-cigarettes: a risk assessment analysis of a recently-published study. *Inhalation Toxicology*, 30(7–8), 321–326. https://doi.org/10.1080/08958378.2018.1523262

128 Farsalinos, K. E. et al. (2015). Evaluation of Electronic Cigarette Liquids and Aerosol for the Presence of Selected Inhalation Toxins. *Nicotine & Tobacco Research*, 17(2), 168–174. https://doi.org/10.1093/ntr/ntu176

is well below recognised safety thresholds but could be reduced still further by improved manufacturing standards.[129]

A 2017 study by Dr William Stephens from the Department of Earth and Environmental Studies at St Andrews University in Scotland calculated that vaping has 0.4 per cent of the cancer risk of smoking (99.6 per cent risk reduction).[130,131]

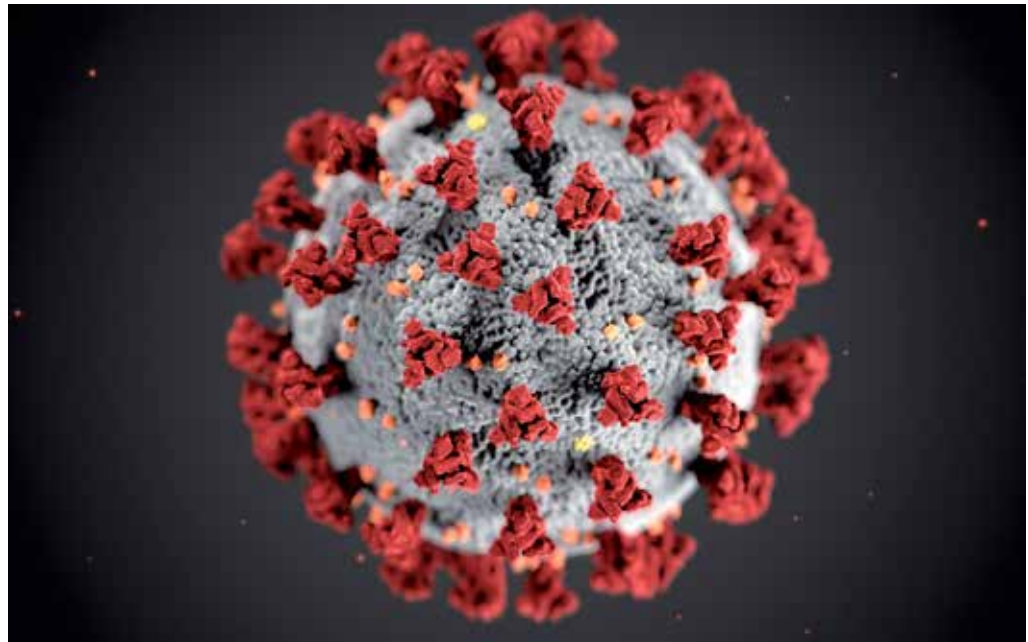## The new pandemic: nicotine, vaping, smoking and COVID-19

Image: CDC on Unsplash

Following hard on the heels of the lung-injury scare, those opposed to THR were only too keen to launch warnings linking vaping to more severe outcomes or susceptibility to COVID-19.

A few studies have shown an association between vaping and lung inflammation which led some to suggest that vapers might be more susceptible to COVID-19. These studies were the result of exposing cell cultures or rats, or small samples of vapers who were invariably ex- or current smokers, to vapour. Longitudinal studies studying vaping in real world situations have not replicated laboratory studies in respect of vaping and lung inflammation or infections.[132]

Moreover, early research has suggested that nicotine could be a protective factor against initial COVID-19 infection and disease progression meaning that smokers are less likely to test positive for COVID-19[133] and less likely to be admitted to hospital but,

[129] Ward, A. et al. (2020). Electronic nicotine delivery system design and aerosol toxicants: A systematic review. *PLOS ONE*, 15, e0234189. https://doi.org/10.1371/journal.pone.0234189

[130] Stephens, W. E. (2018). Comparing the cancer potencies of emissions from vapourised nicotine products including e-cigarettes with those of tobacco smoke. *Tobacco Control*, 27(1), 10–17. https://doi.org/10.1136/tobaccocontrol-2017-053808

[131] Burstyn, I. (2014). Peering through the mist: systematic review of what the chemistry of contaminants in electronic cigarettes tells us about health risks. *BMC Public Health*, 14(1), 18. https://doi.org/10.1186/1471-2458-14-18

[132] Polosa, R. et al. (2017). Health impact of E-cigarettes: A prospective 3.5-year study of regular daily users who have never smoked. *Scientific Reports*, 7. https://doi.org/10.1038/s41598-017-14043-2

[133] Lusignan, S. de et al. (2020). Risk factors for SARS-CoV-2 among patients in the Oxford Royal College of General Practitioners Research and Surveillance Centre primary care network: a cross-sectional study. *The Lancet Infectious Diseases*, 0(0). https://doi.org/10.1016/S1473-3099(20)30371-6

if admitted, have worse outcomes. This has led to a theory that nicotine could be a protective factor as the person would no longer have access to nicotine.[134,135,136,137]

The hypothesis of the protective effect of nicotine is based on (1) the possibility that the interaction of nicotine with nicotinic receptors in the brain might inhibit the proteins that allow the virus to attach to cells and (2) the possibility that nicotine could inhibit the over-reaction of the immune system (the so-called cytokine storm) that in most cases ends up producing massive lung inflammation that overwhelms and kills very ill patients.

To our knowledge, there is no data on vaping status in any of the many published studies on hospitalised or seriously ill COVID-19 patients. It is highly likely that in the chaos of the pandemic, doctors asked patients about smoking status (as they are well used to doing, especially in respiratory care), but that they may not have asked about vaping. This lack of data is problematic for our understanding of any potential interaction between susceptibility to and progress of COVID-19 and vaping status; it is also extremely difficult to disaggregate health impacts that relate to past smoking or present vaping. The medical profession should be encouraged to ask all COVID-19 patients about current and past smoking status and current and past vaping status in order to get the fullest possible picture – which may yet take some considerable time to emerge.

Second-hand vapour is not the same as second-hand smoke

Vaping devices emit 'vapour', a mist-like aerosol. The user absorbs about 90 per cent of the inhaled vapour (86 per cent of glycerol, 92 per cent of propylene glycol, 94 per cent of nicotine and 97 per cent of aldehydes).[138,139]

The exhaled vapour released into the environment is an extremely diluted aerosol whose gas phase is propylene glycol, glycerol and water vapour, with residual doses of pollutants (aldehydes). There are misleading mentions in environmental studies about the presence of harmful fine and hyper fine 'particles' in this aerosol, creating concerns by equating them to suspended particles of air pollution or cigarette smoke.[140]

However, the 'particles' in exhaled (and inhaled) vapour are liquid droplets whose chemical composition closely matches the composition of e-liquids: propylene glycol, vegetable glycerine, nicotine and water.[141] These droplets evaporate and disperse in

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[134]　Clive Bates. (2020, June 1). The Unlikely Savior? Smoking, nicotine and COVID-19: What is going on? *Tobacco Reporter.* https://tobaccoreporter.com/2020/06/01/the-unlikely-savior/

[135]　Joe Gitchell. (2020, June 14). *The Odd Case of Tobacco, Nicotine, and COVID-19*. ConscienHealth. https://conscienhealth.org/2020/06/the-odd-case-of-tobacco-nicotine-and-covid-19/

[136]　Farsalinos, K. et al. (2020). Current smoking, former smoking, and adverse outcome among hospitalized COVID-19 patients: a systematic review and meta-analysis: *Therapeutic Advances in Chronic Disease*. https://doi.org/10.1177/2040622320935765

[137]　A recent UK study of over 8 million patients investigated whether certain drugs used in the treatment of heart problems might put patients at increased risk of contracting COVID-19 and subsequent admission to intensive care. Among a whole range of risk variables studied, the authors concluded that, "there was a small increased risk of both adverse outcomes among ex-smokers compared with never-smokers. The apparent protective association was greatest for heavy and moderate smokers and most markedly on the risk of ICU admission which was 88 per cent lower in heavy smokers compared with non-smokers". Hippisley-Cox, J. et al. (2020). Risk of severe COVID-19 disease with ACE inhibitors and angiotensin receptor blockers: cohort study including 8.3 million people. Heart. https://doi.org/10.1136/heartjnl-2020-317393

[138]　St Helen, G. et al. (2016). Nicotine delivery, retention and pharmacokinetics from various electronic cigarettes. *Addiction (Abingdon, England)*, 111(3), 535–544. https://doi.org/10.1111/add.13183

[139]　Samburova, V. et al. (2018). *Aldehydes in Exhaled Breath during E-Cigarette Vaping: Pilot Study Results*. 6, 1–14. https://doi.org/10.3390/toxics6030046

[140]　For example, Glantz, S. A., & Bareham, D. W. (2018). E-Cigarettes: Use, Effects on Smoking, Risks, and Policy Implications. *Annual Review of Public Health*, 39, 215–235. https://doi.org/10.1146/annurev-publhealth-040617-013757

[141]　David, G. et al. (2020). Tracing the composition of single e-cigarette aerosol droplets in situ by laser-trapping and Raman scattering. *Scientific Reports*, 10(1), 7929. https://doi.org/10.1038/s41598-020-64886-5

seconds[142,143] and are completely unrelated to suspended particles of air pollution or cigarette smoke (which are produced by combustion processes). They pose minimal risk to bystanders.[144,145]

Image: romankosolapov on Adobe Stock

However, large clouds of vapour can cause concern among passers-by who might equate this with cigarette smoke and be concerned about the possible effects of their own inhalation. Large clouds of vapour, for example, when many vapers are vaping high powered devices, can irritate the throat in enclosed spaces, (incidentally, this does not occur with low powered devices or when only one or two vapers are vaping). Many vapers are reasonably discreet about their use, adopting 'stealth vaping', by inhaling less vapour and holding it in.

To quote PHE: "To date, there have been no identified health risks of passive vaping to bystanders"[146] – a view underlined by other recent studies.[147,148]

142 Lampos, S. et al. (2019). Real-Time Assessment of E-Cigarettes and Conventional Cigarettes Emissions: Aerosol Size Distributions, Mass and Number Concentrations. *Toxics*, 7(3), 45. https://doi.org/10.3390/toxics7030045

143 Zhao, T. et al. (2017). Characteristics of secondhand electronic cigarette aerosols from active human use. *Aerosol Science and Technology*, 51(12), 1368–1376. https://doi.org/10.1080/02786826.2017.1355548

144 Scungio, M. et al. (2018). Measurements of electronic cigarette-generated particles for the evaluation of lung cancer risk of active and passive users. *Journal of Aerosol Science*, 115, 1–11. https://doi.org/10.1016/j.jaerosci.2017.10.006

145 Avino, P. et al. (2018). Second-hand aerosol from tobacco and electronic cigarettes: Evaluation of the smoker emission rates and doses and lung cancer risk of passive smokers and vapers. *Science of The Total Environment*, 642, 137–147. https://doi.org/10.1016/j.scitotenv.2018.06.059

146 McNeill A, Brose LS, Calder R, Bauld L & Robson D. (2018). *Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England*. (p. 243). Public Health England. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/684963/Evidence_review_of_e-cigarettes_and_heated_tobacco_products_2018.pdf

147 Glasser, A. M. et al. (2017). Overview of Electronic Nicotine Delivery Systems: A Systematic Review. *American Journal of Preventive Medicine*, 52(2), e33–e66. https://doi.org/10.1016/j.amepre.2016.10.036

148 Zwack, L. M. et al. (2017). *Evaluation of Chemical Exposures at a Vape Shop* (Health Hazard Evaluation Report 2015-0107-3279; p. 30). U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health. https://www.cdc.gov/niosh/hhe/reports/pdfs/2015-0107-3279.pdf

Young people and vaping

The arrival of JUUL on the US market has been another major vaping-related news story since our last report, with exaggerated claims of a teenage 'vaping epidemic' prompting knee-jerk flavour bans across the US and elsewhere.

Changes in the prevalence of smokers and vapers among American youth
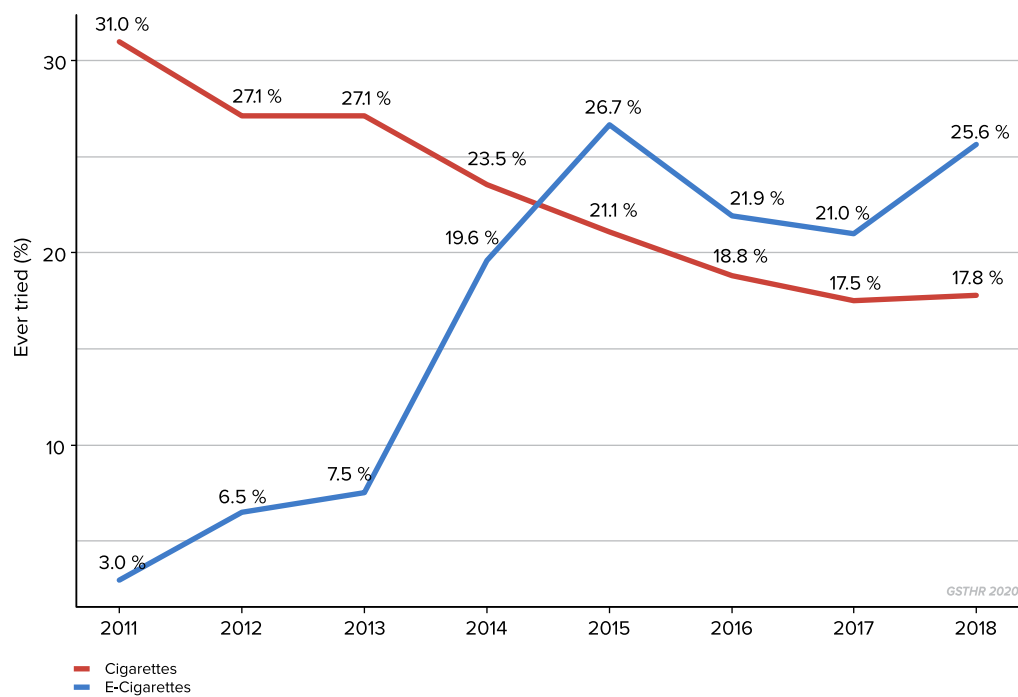
Data source: Office on Smoking and Health. (2018). 2018 National Youth Tobacco Survey (NYTS) [Dataset]. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion. https://www.cdc.gov/tobacco/data_statistics/surveys/nyts/data/index.html

Cigarette smoking has been falling in the US for many years including among young people. When vaping products began to appear on the market, it was inevitable that some young people would want to experiment. This led to claims from the FDA, the Campaign for Tobacco Free Kids (CTFK) and others that vaping was a gateway to smoking as the industry tried to compensate for falling numbers of younger smokers by promoting new products. Yet as the graph shows, cigarette smoking among young people has continued to fall, even while experimentation with vaping devices has been increasing. The goalposts shifted; the claim now from the same bodies is of a vaping "epidemic" among young people which would lead to a future generation of nicotine "addicts". JUUL certainly attracted a lot of interest from some young people when it launched during 2018-19, while the company itself faced accusations of marketing the device to young adults and selling flavours that appeared to be targeting that same younger audience.

The public, the media and legislators continue to be misled over the prevalence of vaping among young people by the simple trick of conflating 'ever use', which could be just once or very infrequent, with 'use'.

However, a study by Allison Glasser and colleagues from New York University (NYU) College of Global Public Health looked at the 2018 National Youth Tobacco Survey of 20,000 middle and high school students and concluded that:

» Over 80 per cent of youth do not use any tobacco product.
» Over 86 per cent don't vape.
» Most youth who do vape are current or former smokers and many are also vaping THC.
» While youth vaping has increased, this was driven by infrequent use.
» Only very few students vaped who had never smoked.[149,150]

Most youth who do vape are current or former smokers and many are also vaping THC.

Image: Drobot Dean on Adobe Stock

Data from the UK ASH revealed a similar picture of occasional use with few younger teenagers vaping and even fewer vaping who had never previously smoked.[151]

If there was any evidence of nicotine-related brain damage in young people, it would have been noted over the many decades of smoking research.

While it might be preferable for young people not to vape, from a health point of view, it is preferable that if young people are going to consume nicotine, better they vape than smoke. The NYU researchers also discovered that over 40 per cent of those students who vaped also smoked cannabis. This research and other studies point to what are called 'shared risk factors' linking vaping, smoking and the use of cannabis among young people.[152,153,154]

Some commentators have claimed that nicotine has a deleterious effect on adolescent brains, causing hitherto unnoticed long-term damage, reducing test scores and inhibiting life chances. If there was any evidence of nicotine-related brain damage in young people, it would have been noted over the many decades of smoking research.[155]

[149] Glasser, A. M. et al. (2020). Youth Vaping and Tobacco Use in Context in the United States: Results from the 2018 National Youth Tobacco Survey. *Nicotine & Tobacco Research: Official Journal of the Society for Research on Nicotine and Tobacco*. https://doi.org/10.1093/ntr/ntaa010

[150] For more detailed information about US teen vaping including the significant but largely ignored increase in teens vaping THC contrasted with dramatic falls in teen smoking, go to:
Rodu, B. (2020, January 10). Tobacco Truth: 2019 NYTS Data Reveals Teen Vaping Up, Smoking Eradication Within Reach. *Tobacco Truth*. https://rodutobaccotruth.blogspot.com/2020/01/2019-nyts-data-reveals-teen-vaping-up.html
Historical NYTS Data and Documentation | CDC. (2019, December 17). https://www.cdc.gov/tobacco/data_statistics/surveys/nyts/data/index.html
Siegel, M. (2020, January 26). The Rest of the Story: Tobacco and Alcohol News Analysis and Commentary: CDC is Concealing and Suppressing Information on Youth Marijuana Vaping to Over-hype Harms of E-Cigarettes. *The Rest of the Story*. https://tobaccoanalysis.blogspot.com/2020/01/cdc-is-concealing-and-suppressing.html

[151] Use of e-cigarettes among young people in Great Britain, 2019. (2019, June 18). *Action on Smoking and Health*. https://ash.org.uk/information-and-resources/fact-sheets/statistical/use-of-e-cigarettes-among-young-people-in-great-britain-2019/

[152] Levy, D. T. et al. (2019). Examining the relationship of vaping to smoking initiation among US youth and young adults: a reality check. *Tobacco Control*, 28(6), 629–635. https://doi.org/10.1136/tobaccocontrol-2018-054446

[153] Kim, S., & Selya, A. S. (2020). The Relationship Between Electronic Cigarette Use and Conventional Cigarette Smoking Is Largely Attributable to Shared Risk Factors. *Nicotine & Tobacco Research: Official Journal of the Society for Research on Nicotine and Tobacco*, 22(7), 1123–1130. https://doi.org/10.1093/ntr/ntz157

[154] Interestingly, the CDC's *Youth Risk Behaviour Survey* for 2017 showed past-30-day cannabis use by high school students at 19.8 per cent, nearly the same as vaping among the same group but with none of the same moral panic. *YRBSS | Youth Risk Behavior Surveillance System | Data | Adolescent and School Health | CDC*. (2020, August 20). https://www.cdc.gov/healthyyouth/data/yrbs/index.htm

[155] Some claims derive from rodent studies which are generally a very poor proxy for real life health risks in humans. Buck, S. (2016, April 8). *Why Journalists Should Stop Publishing Studies Conducted With Mice*. Arnold Foundation. https://www.arnoldventures.org/stories/stop-publishing-mouse-studies/

Options for smoking cessation

Many people quit smoking without recourse to professional help or medical products. Others may combine a range of interventions in a bid to end their smoking habit. Availability of and access to these interventions differs significantly between countries, national health systems and individual socioeconomic status.

Nicotine replacement therapy (NRT)

NRT first appeared in the US in 1984 and over time, various products have come onto the market: patches, chewing gum lozenges, sprays and inhalers. NRT is included in the WHO Essential Medicines List. The principle behind them is that they replace the nicotine, while the smoker perhaps engages with a counselling or stop smoking service for behavioural help in quitting cigarettes.[156] Using more than one NRT product plus counselling within a stop smoking service has been shown to be more effective than just buying NRT at the pharmacy with no other support. NRT products are produced by the pharmaceutical industry; lead players include Pfizer, Novartis, Cipla, Johnson and Johnson and GlaxoSmithKline.

Image: Aintschie on Adobe Stock

Image: RFBSIP on Adobe Stock

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[156] Stop smoking services in England have been hit by significant cuts to public health funding. Services on offer vary across the country, but many are 'vape-friendly'. Many ways forward. (2020, January 14). *Action on Smoking and Health*. https://ash.org.uk/information-and-resources/reports-submissions/reports/many-ways-forward/

Pharmaceutical products

There are two main pharmacotherapeutic options; varenicline (marketed as Champix and Chantix) and bupropion (marketed as Zyban and Wellbutrin). Unlike NRT, these drugs aim to suppress the nicotine craving. Champix works by interfering with nicotine receptors in the brain, preventing the person both from experiencing pleasure and suppressing nicotine withdrawal symptoms. Zyban was initially used to treat depression in patients and also works by diminishing the chemicals in a person's brain that are responsible for cravings and withdrawal symptoms. As with any drugs, both come with a range of possible side-effects and contra-indications.

Image: New Africa on Adobe Stock

There are a several ways out of smoking and people will use a combination of interventions. But for many, these options do not work or do not work over time. For most, the reason is that NRT and drugs do not replicate the smoking experience, and 'medicalise' smoking, which many smokers find unacceptable. Smokers do not necessarily regard themselves as 'ill' simply because they smoke.

Overall, the relapse rates from smoking remain high. As O'Leary and Polosa point out, even for those who do quit smoking, relapse is the norm. For unsupported quit attempts, 80 per cent relapse in the first month and for smokers undergoing treatment, 75 per cent fail within six months, with the large majority resuming smoking within two weeks. The same high relapse rates occur in women in pregnancy and post-delivery and either gender on being discharged from hospital. Even a successful one-year quit does not ensure that abstinence has been achieved as 30 to 40 per cent of former tobacco smokers will eventually relapse. "Consequently, there is a pressing need for alternative and more efficient means to reduce or prevent harm in those who return to smoking".[157]

As a UK ASH/Cancer UK report noted, stop smoking services in England are under funding threat,[158] but they are also seeing fewer people since the advent of vaping devices. This suggests that vaping is an easier off ramp to navigate away from smoking than other methods, whose aim is solely quitting. So how does NRT compare with

[157] O'Leary, R., & Polosa, R. (2020). Tobacco harm reduction in the 21st century. *Drugs and Alcohol Today, ahead-of-print* (ahead-of-print). https://doi.org/10.1108/DAT-02-2020-0007

[158] *A Changing Landscape: Stop Smoking Services and Tobacco Control in England.* (2019). Cancer Research UK and Action on Smoking and Health (ASH). http://ash.org.uk/wp-content/uploads/2019/03/2019-LA-Survey-Report.pdf

vaping when both are used in conjunction with behavioural support in a stop smoking service?

Peter Hajek and colleagues undertook a study whereby nearly 900 smokers who wanted to quit were randomly assigned to NRT or vaping devices plus counselling. The trial ran from 2015–2018 with a one-year follow-up.[159] They found:

> *"Smokers using e-cigarettes suffered less cigarette withdrawal discomfort early on and had higher quit rates at all time points. At 1 year, 10 per cent of participants in the NRT trial arm had been abstinent for the whole year compared with 18 per cent in the e-cigarette arm; regarding abstinence for at least 6 months, the figures were 12 per cent in NRT and 21 per cent in the e-cigarette arm. Of interest, coughs and phlegm production also reduced more in people quitting with e-cigarettes, than those quitting with NRT. This supports previous reports that an ingredient in e-cigarettes (i.e. propylene glycol) may protect vapers from airborne infection. E-cigarette starter packs cost much less than NRT and so if SSS (stop smoking services) provide them, their use is likely to boost the success rates and reduce the costs of SSSs."*

"Smokers using e-cigarettes suffered less cigarette withdrawal discomfort early on and had higher quit rates at all time points."

Low and middle- income countries

As we have outlined, it is LMIC which bear the brunt of the smoking epidemic. Smokers in these countries would be better served if health professionals felt confident to recommend SNP options for those who want to quit smoking. Unfortunately, doctors are being advised against encouraging these options, by researchers and NGOs often from high-income countries, peddling misinformation about the dangers of SNP.[160]

Image: Smith METHA on Unsplash

[159] Hajek, P. et al. (2019). E-cigarettes compared with nicotine replacement therapy within the UK Stop Smoking Services: the TEC RCT. *Health Technology Assessment (Winchester, England)*, 23(43), 1–82. https://doi.org/10.3310/hta23430. For other studies concluding that vaping aids smoking cessation, *see also*; Brown, J. et al. (2014). Real-world effectiveness of e-cigarettes when used to aid smoking cessation: a cross-sectional population study. *Addiction*, 109(9), 1531–1540. https://doi.org/10.1111/add.12623; Jackson, S. E. et al. (2019). Moderators of real-world effectiveness of smoking cessation aids: a population study. *Addiction*, 114(9), 1627–1638. https://doi.org/10.1111/add.14656; Walker, N. et al. (2020). Nicotine patches used in combination with e-cigarettes (with and without nicotine) for smoking cessation: a pragmatic, randomised trial. *The Lancet Respiratory Medicine*, 8(1), 54–64. https://doi.org/10.1016/S2213-2600(19)30269-3.

[160] Novotny, T. E., & Schalkwyk, M. C. I. van. (2020). How Should Physicians in Low- and Middle-Income Countries Regard Electronic Nicotine Delivery Systems to Facilitate Smoking Cessation? *AMA Journal of Ethics*, 22(2), 82–92. https://doi.org/10.1001/amajethics.2020.82.

Therefore, doctors in LMIC are being advised to stick to approved cessation medications when the health systems in many of these countries cannot afford to buy them. Smitha Sarma and colleagues conducted a survey in Kerala, India, and found smoking cessation medications were not available in public hospitals and even in those services offering cessation services. They were only partly available in private and semi-private pharmacies, meaning the poorest people with more acute problems were denied access.[161] As the majority of tobacco users in India do not smoke industry cigarettes but local varieties, including smoke-free products, this suggests that the ready availability of affordable snus-style smokeless products could have significant beneficial health impacts, not only across India but also other countries in the region with similar tobacco-using profiles.

Cessation of smoking using SNP in pregnancy

The harms of smoking during pregnancy include low birth weight, pre-term delivery, increased risk of malformations, respiratory disease and childhood cancers. Cigarette smoke carries all the risks, so it is reasonable to assume that smokeless products carry less risk. The most recent study looking at this issue comes from Glover and Phillips[162] who reviewed the evidence on pregnancy outcomes and smokeless tobacco products.

They identified an initial tranche of 500 studies of which only 21 passed muster to be included. Of the 21 studies reviewed, 12 reported on the use of nicotine replacement therapies, seven on Swedish snus, one on Alaskan iq'mik,[163] and one on vaping products.

Image: Heather MOUNT on Unsplash

161   Sarma Smitha et al. (2017). Availability, Sales, and Affordability of Tobacco Cessation Medicines in Kerala, India. *Circulation: Cardiovascular Quality and Outcomes*, 10(11), e004108. https://doi.org/10.1161/CIRCOUTCOMES.117.004108
162   Glover, M., & Phillips, C. V. (2020). Potential effects of using non-combustible tobacco and nicotine products during pregnancy: a systematic review. *Harm Reduction Journal*, 17. https://doi.org/10.1186/s12954-020-00359-2
163   Iq'mik or blackbull is a smokeless product made using a mixture of tobacco and the ash of a fungus *Phellinus igniarius*, also known as punk ash. It is popular among First Nation Alaskans who believe this product is healthier than US-style dipping tobacco. They may be right, as a related fungus *Phellinus Linteus* is reputed to convey several health benefits. Wong, C. (2020, April 28). *The Health Benefits and Uses for Phellinus Linteus*. Verywell Health. https://www.verywellhealth.com/the-benefits-of-phellinus-linteus-88684

The authors contend that it is not possible to give pregnant women definitive advice on safety, except to say the use of smoke-free nicotine products will almost certainly have less effect on pregnancy outcomes than smoking. They also conclude that if a pregnant woman would otherwise smoke, there is no evidence to deny her access to smoke-free products.

This is similar to the conclusions of the UK's Royal College of Midwives, whose position statement on support for smoking cessation during pregnancy stated:

- – *"E-cigarettes contain some toxins, but at far lower levels than found in tobacco smoke. If a pregnant woman who has been smoking chooses to use an e-cigarette (vaping) and it helps her to quit smoking and stay smoke-free, she should be supported to do so."*
- – *"If a woman has switched completely to vaping and is not smoking at all, she should be recorded as a non-smoker."*
- – *"Based on the available evidence on e-cigarette safety, there is no reason to believe that use of an e-cigarette has any adverse effect on breastfeeding. 'Vaping' should continue if it is helpful to quitting smoking and staying smoke free."*[164]

Nicotine and addiction

The focus on addiction to nicotine as the main risk to young people has gained ground since the last report.

The illustration is a collage of pre-Second World War American newspapers. It shows that in the hands of the supernatural 'drug fiend', drugs like cocaine and heroin become disease vectors, infecting young people with the virus of addiction and – ultimately – destroying their lives.

Silver, G., & Aldrich, M. R. (1979). *The Dope Chronicles*, 1850-1950 (1st edition). Harper & Row.

[164] *Support to Quit Smoking in Pregnancy*. (2019). The Royal College of Midwives. https://www.rcm.org.uk/publications/position-statements/support-to-quit-smoking-in-pregnancy/

Dependency on drugs like cocaine and heroin can and does destroy lives. But this does not apply to nicotine. Yes, lives can be destroyed by smoking and the deaths and disease it causes – but as millions of consumers of SNP around the world would testify, lives have not been destroyed by nicotine, neither physically nor mentally.

The meaning of addiction

Addiction is an ill-defined concept which has been applied to many substances and activities; the whole range of psychoactive drugs, both legal and illegal; gambling; shopping; sex; eating; or playing computer games.

When deemed to be out of control and adversely affecting other areas of life, all these are classified by the medical profession as psychiatric conditions. From a common-sense, real-world point of view, however, there is a clear difference between injecting heroin and buying inordinate pairs of shoes.

In the case of nicotine, from a neuro-biological standpoint, it is a mild stimulant drug which binds to the equivalent receptors in the brain like a key fitting into a lock. Once locked in, nicotine stimulates the release of the neurotransmitter dopamine which is crucial to the reward and reinforcement effects that constitute the drug experience.

Simply put, dopamine could be called 'the good time chemical'; it is responsible not just for the pleasure people derive from intoxication,[165] but also for sexual gratification and the satisfaction of eating, without which humans would die out.

The influence of the senses and the environment

As the Royal College of Physicians report pointed out, however, the rewards and reinforcement of smoking are not just about the specific drug/brain interaction, although of course, the brain has a role to play in all our sensory experiences:

Image: Anna SPOLJAR on Unsplash

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[165] See Ronald K. Siegel Ph.D. (2005). *Intoxication: The Universal Drive for Mind-Altering Substances* (3 edition). Park Street Press. The author details how not only humans throughout history, but also animals seek to alter their state of consciousness.

> *"Continued pairing of the rewarding/reinforcement pairing with specific and sensory and environmental stimuli (which for example, could include the smell of tobacco or the sight of a packet of cigarettes) results in these stimuli also acquiring reinforcing properties."*[166]

This could also involve certain rituals like the first cigarette in the morning, or always having a smoke with a drink or a meal.

Varied interpretations of addiction

From that point of view, nicotine is 'addictive'; people say they crave cigarettes, get 'withdrawal symptoms', feel agitated and irritable and find it hard to concentrate if they run out.

Influenced strongly by the psychiatric and rehabilitation industries, addiction is viewed in society as a disease caused by the brain being 'hijacked'.

Yet 'addiction' to nicotine falls far short of the addiction criteria set out in the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (2013), the gold-standard text on the names, symptoms and diagnostic features of recognised mental illnesses. Here, the features of addiction include taking the substance in larger amounts or for longer than you're meant to; spending a lot of time getting, using, or recovering from use of the substance; not managing to do what you should at work, home, or school because of substance use; continuing to use, even when it causes problems in relationships; giving up important social, occupational, or recreational activities because of substance use and needing more of the substance to get the effect you want.

None of these apply to the use of nicotine on a regular, long-term basis. In fact, people use nicotine to help them in everyday activities like focusing on work. There is some evidence that nicotine might have a role to play in helping those with dementia.[167]

In the public mind, the word 'addiction' conjures up a life in chaos and ruin, where the drug becomes all-consuming, where family and friends, school, college or job, everything in the person's life, takes second place behind securing the next dose which (in the case of illegal drugs) may also involve criminal activity.

But does this picture of misery and despair map across to the person who is 'addicted' to nicotine? Because as the clinical literature confirms, if there are no significant short or long-term effects from using nicotine, and if you take the cigarettes out of the equation by changing the nicotine delivery system, the somewhat heretical question becomes – what's the problem with being 'addicted' to nicotine? In this specific context, should we even talk about 'addiction' at all? In the absence of serious clinical or societal harm, isn't this just a pleasurable habit? In which case, does the concept of 'addiction' become more of a moral or ideological construct than one based in public health?[168,169,170]

'Addiction' to nicotine falls far short of the addiction criteria set out in the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders.

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[166] *RCP policy: public health and health inequality. (2016). Nicotine without smoke: Tobacco harm reduction.* Royal College of Physicians. https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction

[167] Interestingly, researchers from Liverpool University have concluded that this type of categorisation of mental health problems is essentially meaningless in many real world situations where conditions might overlap and where not all human distress can be conveniently labelled as a 'disorder' where the notion of what is 'normal' is subjective. Anderer, J. (2019, July 9). Study: Psychiatric Diagnoses Are 'Scientifically Meaningless' In Treating Mental Health. *Study Finds.* https://www.studyfinds.org/study-psychiatric-diagnoses-are-scientifically-meaningless/

[168] As an interesting aside, there is evidence that nicotine might be more 'addictive' when smoked in cigarettes because of other additives in the smoke to aid nicotine delivery and absorption, including MAO inhibitors, sugars and polysaccharides. RCP policy: public health and health inequality. (2016). *Nicotine without smoke: Tobacco harm reduction.* Royal College of Physicians. https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction, p.61

[169] Some clinicians prefer 'dependence' to 'addiction' and would argue that nicotine 'enjoyment' is simply a manifestation of dependence, keeping the regular use of nicotine within a medical context.

[170] It has also been proposed that reframing smoking as an 'addiction' rather than a 'habit' opened the door to the 'medicalisation' of smoking and a route into a burgeoning and hugely profitable public health issue by the pharmaceutical industry.

Image: Photos Hobby on Unsplash

> For the many people who are unable or unwilling to give up their use of nicotine, it would be invidious to allow guilt and shame about nicotine 'addiction' to inhibit quit or switch attempts using SNP.

This is an important point: in many countries where SNP are available, the law demands prominent warnings on packaging about addiction. But is this really a serious clinical issue? Or is it more an attempt to shame people who use nicotine into feeling guilty? Smokers often cite the guilt and shame of being 'addicted' to nicotine as a reason for trying to quit. People who say they want to stop smoking will sometimes object to switching to SNP as they identify a continued addiction to nicotine to be some sort of failure. But for the many people who are unable or unwilling to give up their use of nicotine, it would be invidious to allow guilt and shame about nicotine 'addiction' to inhibit quit or switch attempts using SNP.

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There should be no doubt that using a vaping device, a HTP or specific smokeless products presents substantially less risk to the smoker who wants to switch away from cigarettes, but who wants the nicotine experience unavailable through NRT. The hope was that all those involved in public health and tobacco control would regard this third way out of smoking as a welcome addition to existing anti-smoking interventions.

Unfortunately, the advent of SNP has provoked the opposite reaction. The public health imperative to reduce the disease and death toll from smoking has arguably been side-lined in favour of a moral crusade against nicotine. This playbook aims to sow confusion about the health benefits of SNP and conflates THR with long-standing attempts by the tobacco industry to influence tobacco control policy. In doing so, researchers and THR activists are smeared as functionaries of Big Tobacco.

Chapter 5
Project fear: the war against nicotine

Following the publication of reports by the Royal College of Physicians and the US Surgeon General in the early 1960s, the battle lines were drawn between the tobacco industry on the one hand and anti-smoking organisations and medical and public health authorities on the other.

For its part, the industry did everything it could to deflect attention away from the lethality of its product; sowing confusion by publishing conflicting evidence; intense lobbying to stymie attempts at regulation; trying to convince smokers that filter cigarettes were safer and so on – while aligning an aspirational lifestyle with smoking, as much as with the product itself.

Cover of Time magazine © after the MSA, 1998

On the other side, US anti-smoking campaigners were doing their utmost to challenge the tobacco companies. Using the growing body of evidence on the baleful effects of smoking, American anti-smoking campaigners scored victories in pushing for legislative change and teamed up with state governments in winning lawsuits against the industry. Ultimately, companies concluded the Master Settlement Agreement (MSA) in November 1998, paying billions of dollars to the states to cover smoking-related health costs (although over the years, much of that money simply went to filling holes in state budgets).[171] And those battles have continued around the world, with plain

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[171] Chretien, S. (2017, December 12). *Up In Smoke: What Happened to the Tobacco Master Settlement Agreement Money?* Citizens Against Government Waste. https://www.cagw.org/thewastewatcher/smoke-what-happened-tobacco-master-settlement-agreement-money

packaging legislation, bans on advertising and public smoking and ever-higher rates of taxation. But there is a sting in the tail.

The new nicotine products have been disruptive to the tobacco industry which has had to adapt or get left behind in a burgeoning market. The development of SNP has also been hugely disruptive to the deeply embedded narrative of anti-smoking campaigners. The growing use of SNP and the re-evaluation of the relative benefits of smokeless tobacco has split the global public health community. It has generated a new era of uncertainty and confusion around nicotine consumption. The long-standing 'heroes and villains' narrative has been disrupted to the extent that – regarding THR – some major 'heroes' of the tobacco wars are now public health 'villains' who are putting smokers' lives at risk.

New safer nicotine products have been disruptive both to the tobacco industry and to tobacco control.

What started out in the 1960s as a war against smoking, over time became an issue of international tobacco control. Thanks to the new generation of smoke-free products, the over-arching strategy now reveals itself as a 'war against nicotine': in effect, a war against consumers.

From the 1970s onwards, the message about the dangers of smoking began to permeate populations in high income countries, coupled with increasing enthusiasm for a healthier lifestyle. Smoking levels were falling in these countries as the campaign against smoking gained the upper hand.

It should be the mission of every health-related NGO to close should its disease of focus be eradicated. Instead, rather than disappear, they often re-invent themselves.[172] Within the anti-smoking realm, US NGOs such as the CTFK had been dealing with a diminishing cause, as smoking among teenagers was also falling in line with adult rates. However, the arrival of vaping devices on the US and European markets in 2006/07 was manna from heaven for those who wanted to continue to fight the good fight – even at the expense of those likely to benefit from nicotine innovations.

The narrative which followed this seismic shift in the tobacco landscape was and remains messy and controversial. It's driven by a mix of reactivity, polarised position-driven analysis and campaigning interests, emotive media reporting, hidden conflicts of interest and adversarial relationships between scientists, experts and policymakers, along with an increasingly contested evidence base.

Moral entrepreneurs seek to impose their own standpoints on society at large. They generate moral panic by expressing the conviction that a threatening social evil exists.

Two overlapping sociological concepts help understand what is going on. One is the role of moral entrepreneurs who seek to impose their own standpoints on society at large.[173] The second are availability heuristics, or put more simply, confirmation bias – whereby the public and the media fail to check information, and simply accept cascaded wisdom from ostensibly trusted sources based on gut reactions or plausibility. In other words, relying on information we instinctively think we know to be true.[174]

Moral entrepreneurs can be individuals, religious groups or formal organisations who press for the creation or enforcement of a 'norm' for any number of reasons, altruistic or selfish. They generate moral panic by expressing the conviction that a threatening social evil exists that must be combated and are not unduly concerned with the means of achieving their desired outcome.

172 Minton, M. (2018). *Fear Profiteers. How E-cigarette Panic Benefits Health Activists.* (Issue Analysis). Competitive Enterprise Institute. https://cei.org/content/fear-profiteers
173 Those who campaigned against slavery in the 19th century and more recently, climate change, environmental damage, racism and many other issues of ethics and conscience are beacon examples of how moral entrepreneurs can be a force for good. This contrasts with the intentions of those campaigning against tobacco harm reduction.
174 Tversky, A., & Kahneman, D. (1974). Judgment under Uncertainty: Heuristics and Biases. *Science*, 185(4157), 1124–1131. https://doi.org/10.1126/science.185.4157.1124

Harry Anslinger and the marijuana moral panic

Source: Wikimedia Commons
Harry Anslinger (centre), flanked by Col. C.H.L. Sharman, Chief of Canadian Narcotic Control (left) and Assistant Secretary of Treasury Stephen B. Gibbon (right), in 1937.

Care needs to be taken in attributing significant developments in public discourse to one individual. But it would not be stretching a point to identify Harry Anslinger as the architect of America's moral panic around marijuana in the 1930s. A classic example of the moral entrepreneur, he was given the job of creating the Federal Bureau of Narcotics after a failed career trying to enforce alcohol prohibition.

The new agency was short of funds, while the newspapers were full of the well-rehearsed threat of drugs like cocaine and heroin. Anslinger realised the best way to attract Congressional money was to manufacture a new drug scare. The easy targets for this were already despised immigrants from Mexico and those on the edges of society like musicians, small time crooks and sex workers, who together comprised a majority of marijuana consumers. Anslinger combed the crime records to find examples of murders committed by immigrants supposedly under the influence of marijuana. With the willing assistance of faith and moral reforming groups, doctors and a salacious press, he promulgated the idea that marijuana drove people homicidally mad.

The narrative was extended to the now familiar 'threat to young people' in a cascade of articles and lectures, culminating in his film *Reefer Madness*. By the 1950s, however, the trope was wearing a bit thin, even with politicians. To secure more funding, he changed tack and suggested that while marijuana itself did not necessarily drive people to madness, it did lead them inexorably through the gate to the world of 'hard' drugs.

Anslinger succeeded due to a climate of general ignorance about the drug. The wider public had little personal experience of marijuana. The information was coming directly from his office, delivered by credible sources such as Anslinger himself and doctors in white coats, to a public and a press prepared to believe the worst about Mexican immigrants.

Harry Anslinger, as head of the Federal Bureau of Narcotics, scared the American public by suggesting that marijuana was a gateway to hard drugs.

Stanton Glantz

In the same vein, long-time anti-tobacco activist Stanton Glantz from the University of California turned his attention to SNP shortly after tobacco companies expressed an interest in the market. He has been able to create an Anslinger-like cascade of misinformation through the publication of numerous papers and many conference and media appearances. These have also served to keep government grants flowing to his employer, amounting to millions of dollars over many years. Like Anslinger, he is an archetypal moral entrepreneur and is seen by many as the go-to expert on a subject around which swirls much ignorance.

Protestor holding sign against vaping. Image: AndriiKoval on Adobe Stock

During his time fighting the war against smoking, Glantz made this assertion about his research priorities during the Q&A session of a tobacco conference in 1992. "If it comes out the way I think, will it make a difference? And if the answer is 'yes' then we do it, and if the answer is 'I don't know' then we don't bother. Okay? And that's the criteria."[175]

It is hard to come to any other conclusion than Glantz looks for ways to deliver the bad news before he starts, similarly known in scientific circles as *confirmation bias*. This has carried over into anti-vaping research.

His research in this area is often subject to severe criticism by peer researchers. Two examples will suffice.

In 2015, Glantz published a meta-analysis to claim that smokers who vaped reduced their chance of quitting by 28 per cent. However, he selected only those studies of current smokers who had previously vaped and, obviously for that group, vaping didn't work.[176]

Unexpected criticism of the paper came from the American Legacy Foundation or Legacy, a leading tobacco control research and policy NGO established in 1998. It was a beneficiary of the MSA, receiving what amounted to a start-up grant of $1.55bn. In 2001, the Foundation granted $15m to the University of California in San Francisco to

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[175] Snowdon, C. (2009). *Velvet Glove*, Iron Fist: A History of Anti-Smoking. Little Dice. P.167

[176] Glantz, S. (2015, March 14). *Meta-analysis of all available population studies continues to show smokers who use e-cigs less likely to quit smoking*. Center for Tobacco Control Research and Education. https://tobacco.ucsf.edu/meta-analysis-all-available-population-studies-continues-show-smokers-who-use-e-cigs-less-likely-quit-smoking

establish a library of tobacco industry documents and created an endowed chair held by Stanton Glantz. Surprising then, that the agency would openly criticise a Glantz paper. Except the scientists who worked for Legacy – before it was renamed the Truth Initiative (TI) – adhered to good scientific standards and backed tobacco harm reduction. [see box on next page].

Legacy staff wrote a detailed literature review on THR products which was sent to the FDA ahead of three FDA evidence review workshops. At the time, the Glantz study was only available on the university website, to which the Legacy review referred in its notes. Legacy observed:

> *"While the majority of the studies we reviewed are marred by poor measurement of exposures and unmeasured confounders, many of them have been included in a meta-analysis that claims to show that smokers who use e-cigarettes are less likely to quit smoking compared to those who do not. This meta-analysis simply lumps together the errors of inference from these correlations. As described in detail above, quantitatively synthesizing heterogeneous studies is scientifically inappropriate and the findings of such meta-analyses are therefore invalid."*[177]

With his junior colleague Sara Kalkhoran, Glantz went on to publish the study in Lancet Respiratory Medicine in 2016,[178] only to be sharply criticised by tobacco experts writing for independent science communication charity, the Science Media Centre. Professor Ann McNeill from the National Addiction Centre in London said:

> *"This review is not scientific. The information included about two studies that I co-authored is either inaccurate or misleading. In addition, the authors have not included all previous studies they could have done in their meta-analysis. I believe the findings should therefore be dismissed. I am concerned at the huge damage this publication may have caused – many more smokers may continue smoking and die if they take from this piece of work that all evidence suggests e-cigarettes do not help you quit smoking; that is not the case."*[179]

A second paper met with an even harsher reaction – a retraction from the publishing journal. In June 2019, Glantz and Dharma Bhatta published a paper in the journal of the American Heart Association. It claimed that smoking and vaping posed an equal risk of heart attack, with dual use putting vapers at even more risk. The claim received widespread media coverage.

In response, Professor Brad Rodu from the University of Louisville, Kentucky, performed his own analysis on the same data used by Glantz. Rodu ascertained that those who had suffered heart attacks had done so before they started vaping.

Rodu wrote to the journal demanding a retraction. This was followed up by a supporting letter backing retraction, signed by several public health scholars. Journals are loathe to retract papers as it exposes weaknesses of their peer review process. Eventually, the paper was retracted – under an excuse that Glantz did not have access to all the data, prompting him to claim the journal has been got at by 'e-cig interests'.[180]

[177] https://web.archive.org/web/20151026231500/truthinitiative.org/sites/default/files/2015.06.30%20E-Cig%20FDA%20Workshop%20Docket%20FINAL.pdf – p.12

[178] Kalkhoran, S., & Glantz, S. A. (2016). E-cigarettes and smoking cessation in real-world and clinical settings: a systematic review and meta-analysis. *The Lancet*. Respiratory Medicine, 4(2), 116–128. https://doi.org/10.1016/S2213-2600(15)00521-4

[179] Expert reaction to meta-analysis looking at e-cigarette use and smoking cessation. (2016, January 14). *Science Media Centre*. https://www.sciencemediacentre.org/expert-reaction-to-meta-analysis-looking-at-e-cigarette-use-and-smoking-cessation/

[180] McDonald, J. (2020, February 20). Journal Retracts 'Unreliable' Glantz Study Tying Vaping to Heart Attacks. *Vaping360*. https://vaping360.com/vape-news/88729/journal-retracts-unreliable-glantz-study-tying-vaping-to-heart-attacks/

Image: Pixelot on Adobe Stock

These examples raise serious questions about the validity of research when conducted by those also engaged in campaigning activities linked to their research. Former UK ASH Director and equally fervent anti-THR advocate Mike Daube tellingly agrees that research is compromised by campaigning. Referring to pioneering British tobacco researchers Richard Doll and Bradford Hill's refusal to engage in anti-smoking activities, he said "the researcher is seen to lose his objectivity as soon as he becomes a campaigner".[181]

Legacy and The Truth Initiative (TI)

In addition to funding an endowed chair and the tobacco industry documents library at the University of California San Francisco, The American Legacy Foundation established the Steven A. Schroeder Institute for Tobacco Research and Policy Studies (SITRPS) as a national resource to conduct science to inform tobacco and nicotine policy. From 2008 until about 2016, the SITRPS conducted research, systematic reviews and commentaries, while also communicating its work more widely with public-facing fact sheets. The research reflected the SITRPS scientists' initial scepticism about harm reduction, but their support grew in accordance with the evidence. They were backed by The Legacy leadership of then-president and CEO Dr Cheryl Healton and Chief Operating Officer David Dobbins. Both Healton and Dobbins signed the letter attached to the 2015 literature review, which was sent to the FDA, as well as several other documents and testimony presented at FDA hearings on what the best science reflected at the time.

When Cheryl Healton left and Legacy entered a year of transition, the Legacy board of directors' chair, Iowa State Attorney-General Tom Miller, continued to back the science-based approach to tobacco harm reduction. Everything appeared to change between 2015–2018. Former ad agency executive Robin Koval was appointed as President and CEO, while Tom Miller left the now renamed TI board in 2018 having completed his nine-year stint. The organisation's work became focused on youth prevention and took on an entirely prohibitionist approach.

181 Berridge, V. (2007). *Marketing Health: Smoking and the Discourse of Public Health in Britain*, 1945-2000 (1 edition). Oxford University Press.

Subsequently, almost all the Schroeder Institute's leadership and core research faculty left for other positions in 2016-2018. Within a year of the leadership changes, material in support of harm reduction was removed from the TI website. The organisation now aligned itself with the anti-harm reduction ideology of the CTFK. SITRPS was incorporated into existing TI program evaluation infrastructure and is similarly aligned with the TI's advocacy and ideological goals.

Risk perception

Just how much damage is being done can be seen by the worsening perception of the relative safety of SNP among existing smokers.

Even in the UK, where the government and public health authorities have taken a world-leading pragmatic approach to THR and publicised support for switching, the proportion of smokers believing that smoking and vaping are equally harmful has increased from 28 per cent in the last quarter of 2014 to over 50 per cent in the first quarter of 2020. In the first quarter of 2020, a further 20 per cent said that vaping was more harmful than smoking .[182] This means most smokers believe that vaping is as harmful or more harmful than smoking. To quote the latest Public Health England report on vaping in England: "It is of concern that negative beliefs about the harms from vaping might prevent smokers from switching to vaping and they would therefore continue to be exposed to the extremely high levels of harm caused by smoking."[183]

73 per cent

the proportion of smokers in the UK who now believe that vaping is as harmful or more harmful than smoking.

Harm perceptions of e-cigarettes compared with cigarettes
N=19239 current smokers who do not currently use e-cigarettes
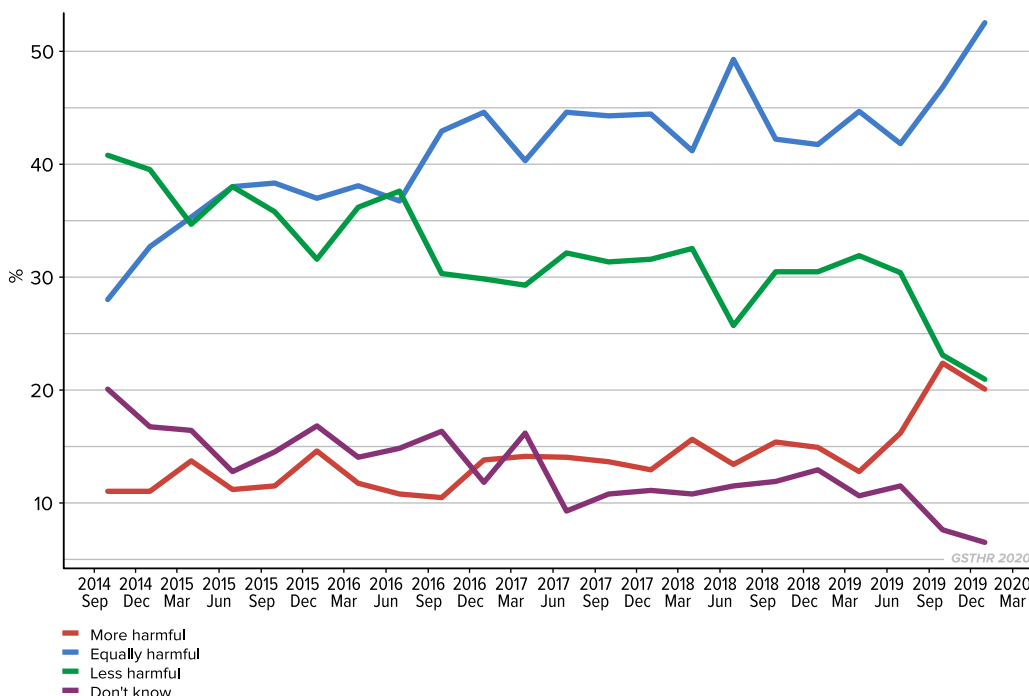
Robert West et al. (2020). *Trends in electronic cigarette use in England* [Smoking Toolkit Study]. Smoking in England.
http://www.smokinginengland.info/sts-documents/

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[182] Robert West et al. (2020). *Trends in electronic cigarette use in England* [Smoking Toolkit Study]. Smoking in England. http://www.smokinginengland.info/sts-documents/
[183] McNeill, A. et al. (2020). *Vaping in England: an evidence update including mental health and pregnancy* (Research and Analysis) [A report commissioned by Public Health England]. Public Health England (PHE). https://www.gov.uk/government/publications/vaping-in-england-evidence-update-march-2020/vaping-in-england-2020-evidence-update-summary

In the US, a survey concluded that smokers' perceptions of the relative safety of SNP over cigarettes worsened between 2008–2017. That was before the public scare about cases of VITERLI illnesses and deaths.[184] The picture is the same in Canada. The Angus Reid Institute conducted a general population survey about vaping and found that the number of vapers in Canada is on the rise; from just 9 per cent of smokers having tried vaping in 2013 to 25 per cent in 2019. 74 per cent of those questioned said either that they had vaped or that they knew friends or family who had. Yet those who thought vaping did more harm than good increased significantly in just 12 months – from 35 per cent in 2018 to 62 per cent in 2019.[185]

Follow the money

Image: Sharon McCUTCHEON on Unsplash

While it might appear that organisations across the world are operating independently in their opposition to THR, the reality is that they are bound together by one critical element – money.

While it might appear that organisations across the world are operating independently in their opposition to THR, the reality is that they are bound together by one critical element – money.

The US is the epicentre for all anti-THR funding across the world, and what follows focuses on US funding structures. There are two primary sources of income for those who are actively campaigning against THR. The first is US federal and state funding for domestic campaigns. The second is donor funds, provided mainly by Bloomberg Philanthropies (BP) with support from the Bill and Melinda Gates Foundation (BMGF), for domestic US and global campaigning and policy work. Funding has also been provided for anti-THR campaigning by a pharmaceutical industry anxious to protect its smoking cessation product interests.

The USA is the epicentre for all anti-THR funding across the world.

US Government[186]

Money flows downwards from the Department of Health and Human Services (HHS), who in turn have to compete with all the other departments in convincing Congress of

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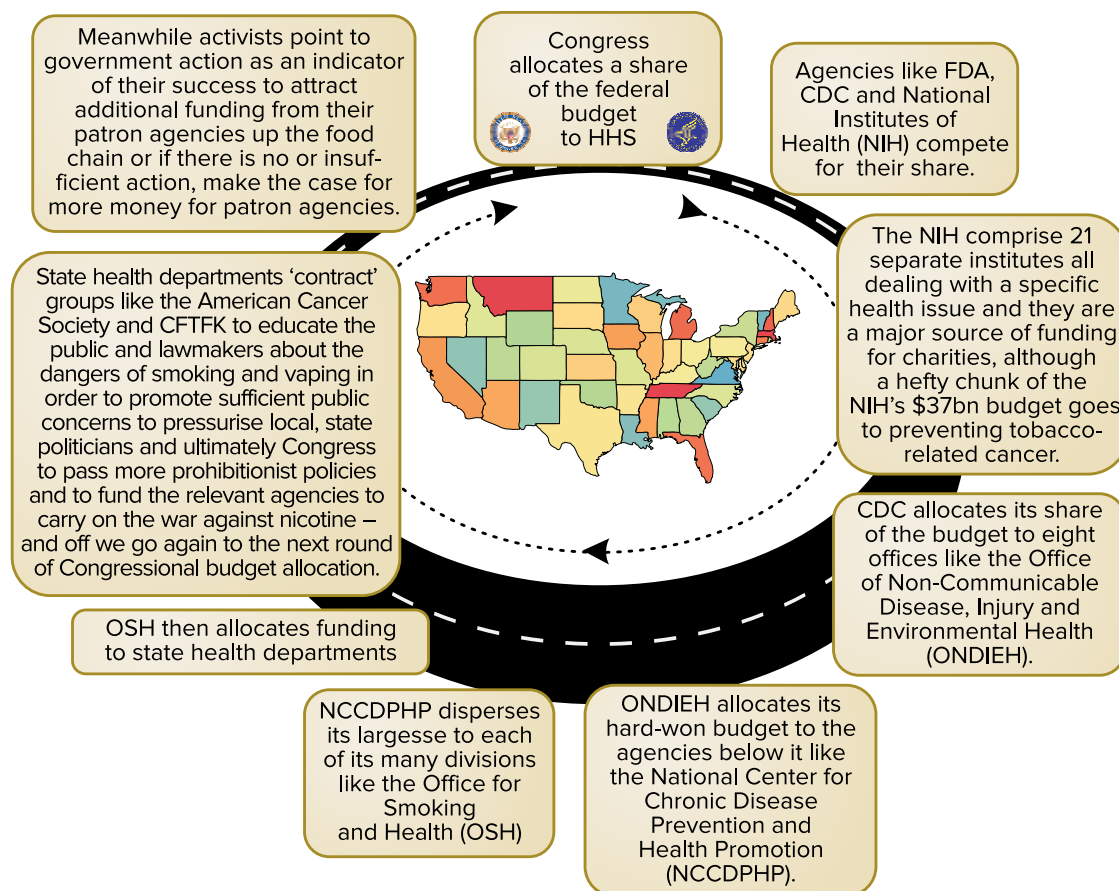[184] Poster presented at the Society for Research on Nicotine and Tobacco conference 2018
[185] Vanquishing vaping? Support for tougher regulations rise as positive views of e-cigarettes go up in smoke. (2020, January 6). *Angus Reid Institute*. http://angusreid.org/vaping-trends-canada/
[186] Information for this section kindly provided by Michelle Minton of the Competitive Enterprise Institute, Washington.

the value of their services in the fight for a share of the Federal budget. However, once a budget is secured, agencies within the HHS like the FDA, CDC and National Institutes of Health (NIH) are in competition for a slice of the pie. They all understand there is nothing more effective at loosening the public purse strings than declaring an epidemic that must be tackled.

But these agencies need to prove their case – and this is where a co-dependency cascade begins. The hottest health topic before COVID-19 was the outbreak of vaping-related deaths, which helped solidify the dangers of the alleged epidemic of youth vaping. This was the subject most likely to attract HHS budget holders.

The US government funding roundabout looks like this:

Meanwhile activists point to government action as an indicator of their success to attract additional funding from their patron agencies up the food chain or if there is no or insuf-ficient action, make the case for more money for patron agencies.

Congress allocates a share of the federal budget to HHS

Agencies like FDA, CDC and National Institutes of Health (NIH) compete for their share.

State health departments 'contract' groups like the American Cancer Society and CFTFK to educate the public and lawmakers about the dangers of smoking and vaping in order to promote sufficient public concerns to pressurise local, state politicians and ultimately Congress to pass more prohibitionist policies and to fund the relevant agencies to carry on the war against nicotine – and off we go again to the next round of Congressional budget allocation.

The NIH comprise 21 separate institutes all dealing with a specific health issue and they are a major source of funding for charities, although a hefty chunk of the NIH's $37bn budget goes to preventing tobacco-related cancer.

OSH then allocates funding to state health departments

CDC allocates its share of the budget to eight offices like the Office of Non-Communicable Disease, Injury and Environmental Health (ONDIEH).

NCCDPHP disperses its largesse to each of its many divisions like the Office for Smoking and Health (OSH)

ONDIEH allocates its hard-won budget to the agencies below it like the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP).

GSTHR 2020

Agencies like the FDA and CDC often consult with and take briefings from a number of long-established, well-funded and influential health advocacy groups. To the public, these groups appear to be generating advice that is based on medical and scientific expertise, in the service of public well-being and absent of any bias. However, groups like CTFK, backed by advocacy-driven research, are in fact acting as moral entrepreneurs. They are generating the marketing and press releases which stimulate public concern.

While the media provide the public megaphone, NGOs engage in the kind of political activism forbidden to government agencies, putting pressure on politicians and legislators to act in the face of public clamour. In fact, politicians and government officials need external allies to give the impression they have responded positively to community concerns; proof they are listening to the people. As Franklin Roosevelt famously said, "OK. You've convinced me. Now go out there and bring pressure on me."

Philanthrocapitalism

The second and more significant financial input into both US and global campaigning against THR has come from Bloomberg Philanthropies (BP), with some assistance from The Bill and Melinda Gates Foundation (BMGF).

Foundation funding is differentiated from other forms of charitable financing as there are no public donations, government or other charitable third-party funding. Money derives from the profits of the founder's business and investment interests. Foundations are nothing new; the Rockefeller Foundation was established in 1913; the Ford Foundation in 1936. A new ethos driving modern day philanthropy applies management methods and metrics to the running of philanthropic projects on the basis that doing good is good for business.

The most significant financial input into US and global campaigning against THR has come from Bloomberg Philanthropies with some assistance from the Bill and Melinda Gates Foundation.

The term *philanthrocapitalism* was coined in 2006 in *The Economist* by two economists Matthew Bishop, New York bureau chief for The Economist, and Michael Green, previously employed in the UK Department for International Development, who celebrated this new approach in their 2008 book *Philanthrocapitalism: how the rich can save the world*.

Bishop and Green argued that the hallmarks of globalisation, such as the removal of trade barriers and cheap air travel, put countries at greater public health risk of both communicable (infections) and non-communicable diseases caused by drinking, smoking and unhealthy diets. However, many countries, especially LMIC, were ill-equipped to deal with all forms of disease, especially in the wake of the financial crash of 2007-08. Moreover, the crash also impacted on higher income countries, limiting their ability and willingness to contribute to organisations like the WHO. So, the super-wealthy weighed in to 'do their bit'.

Source: Wikimedia Commons
Bill Gates, The Bill and Melinda Gates Foundation.

And quite a bit it turned out to be. The BMGF was established in 2000, from the personal Microsoft fortune of Bill Gates. In 2006, BMGF was gifted $37bn by Warren Buffet from his own investment fund and now has assets worth close to $50bn distributed primarily in support of overseas infectious disease control and agriculture, and US education. Michael Bloomberg had been donating to US-based causes since

the mid-1980s, backed by personal wealth, also in the region of $50bn. International tobacco control was his first major foray overseas.
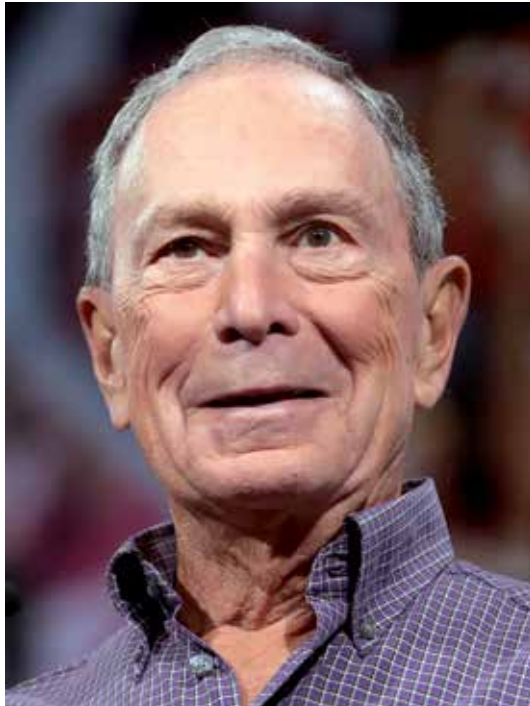
Source: Wikimedia Commons
Michael Bloomberg, Bloomberg Philanthropies.

As Bill Gates explained in *Time* magazine in July 2008, the name of the game was not simply altruism, but a large element of 'what's in it for me?' as an investor in philanthropic work. What he called 'creative capitalism' meant doing good in poorer countries – by increasing their health and wealth, in the expectation that they would then become consumers. And he was not shy about this, quoting one study that found "the poorest two-thirds of the world's population has $5 trillion in purchasing power."[187]

Source: Wikimedia Commons
The BMGF Discovery Center, Seattle, US.

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[187] Kiviat, B., & Gates, B. (2008, July 31). Making Capitalism More Creative. *Time*. http://content.time.com/time/magazine/article/0,9171,1828417,00.html

Then there is the issue of funding programmes aimed at non-communicable diseases, where public health officials attempt to influence population lifestyles. This can easily tip over into a development agenda driven as much by the moral outlook of funders, policy makers and programme managers as activities geared to maximise public health. Given that those in the middle and upper levels of the funding hierarchy are mainly from the 'Global North', arguably there is a neo-colonial angle to international tobacco control, whose programmes would hardly exist without Bloomberg's millions.

International tobacco control programmes would hardly exist without Bloomberg's millions.

Over the past 15 years, a tangled web of well-funded, well-organised, inter-dependent grantees, sub-grantees, associates and partners has spun out across the world. The programmes being funded have increasingly morphed into industry-obsessed, anti-nicotine programmes directed as much, if not more, against tobacco harm reduction as reducing harm from smoking.

How has this come about?

Michael Bloomberg became Mayor of New York on 1st January 2002. Health services in the city are run under the auspices of the NY City Health Department (NYCHD), headed up by the Health Commissioner, a political appointment. The incoming Mayor appoints the Health Commissioner. The Commission put together a shortlist of potential candidates. On that list was a 'wild card': Tom Frieden.

Frieden's mentor at Edinburgh University, where he had conducted his post-doctoral research, was Sir John Crofton, a pioneer in the treatment of TB and, from the 1950s onwards, an ardent anti-tobacco campaigner. His wife Eileen Crofton founded ASH in Scotland, becoming its first director. Another disciple of Crofton was Judith Mackay, a well-known figure on the international tobacco control scene, working mainly in LMIC.

Frieden had been a public health doctor in NYCHD, heading up the Bureau of TB Control. He was a champion of 'directly observed therapy short courses' (DOTS) for TB, which worked on the principle that more people would be cured of TB if their full course of treatments was directly observed by a health worker, rather than allowing the patient to self-administer and run the risk of non-compliance. Using this strategy, Frieden was credited with turning around New York City's TB outbreak of the early 1990s.

While NYCHD were considering candidates for Commissioner, Frieden was seconded to India to run another DOTS programme. Accompanying Frieden to manage the US International Development money for the programme was Jose Luis Castro, a finance officer also from NYCHD.

To be considered for the post of Health Commissioner was a significant jump in seniority for Frieden. He went back to New York, was interviewed by Bloomberg, and reputedly said he would take the job if Bloomberg did something about smoking in New York City. Frieden was kicking at an open door: Bloomberg had been a 60-a-day smoker but was now on the road to Damascus. By 2003, driven by Frieden, Bloomberg had raised cigarette taxes in NYC, established a quit line and social services for smokers and launched massive anti-smoking campaigns overseen by Sandra Mullins, Director of NYC health communications. Most significantly, Bloomberg and Frieden successfully implemented a smoking ban in bars and restaurants, which resulted in a significant adult smoking decline in NYC and became a model for other cities.

Presumably because of his overseas experience with DOTS and keen to replicate the tobacco control successes in New York, Frieden convinced Bloomberg to pump $125m over two years into international tobacco control efforts in the worst affected poorer

countries. There was no Gates-style Foundation, so the money was to be dispersed through the Bloomberg Partners (see below).

Meanwhile, other limited foundation funding was in play. From 2000–2006, George Soros' Open Society Institute (OSI) had been funding tobacco control programmes in Central and Eastern European and former Soviet Republics. With its track record of funding drug and harm reduction programmes, OSI could not understand the attitude of some mainstream tobacco control activists who even then had no time for the limited tobacco harm reduction options available.

In 2005, OSI convened a meeting in New York which brought together harm reduction experts, including smokeless tobacco researcher Professor Brad Rodu, with tobacco control experts. The dialogue was robust but inconclusive and, a year later, OSI ended its funding for tobacco control.

Before OSI stopped funding tobacco control, it drew attention to how little was spent on the issue: a survey found that outside of national programmes, the total amount of spend on international tobacco control was only $27m a year. In early 2006, OSI convened a meeting bringing together leading funders including major cancer charities, the WHO, the World Bank, the UK Department for International Development and BMGF.

BMGF, which had just received its $37bn Buffet windfall, started to develop a $300m+ programme which would start small in a few countries and build up the proof of concept to roll out more widely. However, before the Gates programme could get off the ground, the Bloomberg Global Initiative to Reduce Tobacco Use was duly announced in August 2006.

Then in July 2008, Bill Gates appeared with Michael Bloomberg at a New York City media event to announce a combined commitment of $500 million in tobacco control grants, focused primarily on building the evidence base, social marketing, and policy interventions in China, Southeast Asia, and Africa. Later still, Gates and Bloomberg each donated $5m to a multi-donor trust fund used by the World Bank to fund tobacco tax experts advising LMIC.[188]

The Bloomberg programme was initially delivered by the Bloomberg Partners: the CTFK, John Hopkins Bloomberg School of Public Health, the CDC Foundation and the World Lung Foundation (WLF). The WLF was an American-based entity, a partner organisation to the Paris-based International Union Against TB and Lung Disease (The Union) to take in funds from US donors, allowing the donor (including Bloomberg) to earn tax relief. It acted as the conduit for funding other Bloomberg partners, including The Union and the WHO Tobacco Free Initiative (TFI).

Jose Luis Castro moved from NYCHD to become financial director of The Union, then in 2013, became its Executive Director and led the transformation of the WLF into Vital Strategies (VS), of which he is now President and CEO.

VS has funded The Bureau of Investigative Journalism and Bath University's Tobacco Control Research Group which hosts Tobacco Tactics and is a partner in the STOP Campaign. [see box over page]

President Obama appointed Tom Frieden as Director of the CDC in 2009. Frieden left when Trump took over and established Resolve, an initiative of VS, with $225m from BP, BMGF and the Chan Zuckerberg Foundation, whose remit is reducing

Over the past 15 years, a tangled web of well-funded, well-organised, inter-dependent grantees, sub-grantees, associates and partners has spun out across the world.

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[188] http://documents.worldbank.org/curated/en/591281478711961885/pdf/The-Bloomberg-Family-Foundation-Inc-TF072332. pdf; http://documents.worldbank.org/curated/en/293351478711058473/pdf/Official-Documents-TF072332-Bill-and-Melinda-Gates-Foundation-Tobacco-Control-Program.pdf

Source: Wikimedia Commons
Dr. Thomas Frieden, speaking in his role as Director of the CDC in 2014.

cardiovascular disease and preventing epidemics globally. Because of Frieden's experience in infectious disease epidemics, he is now coordinating Bloomberg's funding of COVID-19 programmes. Frieden is listed as a VS trustee in the organisation's Inland Revenue Service submission, alongside his near half a million-dollar Resolve salary.

Since 2006, Bloomberg has donated close to $1 billion to promote anti-tobacco efforts, making BP the developing world's biggest funder of tobacco-control initiatives. In 2013, it was reported that Bloomberg had donated 556 grants in 61 countries to campaigns against tobacco. In August 2016, the WHO appointed Bloomberg as its Global Ambassador for Noncommunicable Diseases.

$1 billion

the amount donated by Bloomberg to anti-tobacco efforts.

Gates and Bloomberg brought in business practices from Microsoft and Bloomberg Media insisting that grantees produce data to demonstrate outcomes and impact.[189] Where millions of dollars are at play, forensic accountability sounds eminently sensible.

Yet there are serious concerns that while demanding openness and transparency, Big Philanthropy itself has highly secretive decision-making processes, and rather than focusing on in-country needs, instead tends to focus on the personal interests of the founder (like Bloomberg and smoking). Critics also charge that it is mainly interested in short-term funding to achieve quick policy wins for maximum publicity, over actual implementation and longer-term investment.[190]

For example, although BP grantees operate in a number of countries, the officials of the WHO TFI are not involved in grant-giving decisions.[191] Grantees and sub-grantees are often locked in what one critic describes as 'group think', creating a cartel mentality,[192] which discourages debate on the way programmes are being managed. Then again, self-censorship for fear of losing funding is a gravitational force that makes coercion unnecessary.

The Bloomberg Initiative's 'audit culture' pushes advocates to strive for outputs that can be measured and documented, such as meetings with legislators, leaflets, workshops and phone calls to journalists. These, however, may not lead directly to

189 Reubi, D. (2018). Epidemiological accountability: philanthropists, global health and the audit of saving lives. *Economy and Society*, 47, 1–28. https://doi.org/10.1080/03085147.2018.1433359
190 McGoey, L. (2012). Philanthrocapitalism and its critics. *Poetics*, 40(2), 185–199. https://doi.org/10.1016/j.poetic.2012.02.006
191 Mukaigawara, M. et al. (2018). Balancing science and political economy: Tobacco control and global health. *Wellcome Open Research*, 3, 40. https://doi.org/10.12688/wellcomeopenres.14362.1
192 Youde, J. (2013). The Rockefeller and Gates Foundations in Global Health Governance. *Global Society*, 27, 139–158. https://doi.org/10.1080/13600826.2012.762341

enforcement of regulations or a long-term decline in tobacco use. Bloomberg Initiative grants awarded to African advocacy groups between 2007 and 2017 shows that of the 79 grants, 51 made to 17 different countries were intended to support passage of comprehensive legislation and/or taxes.[193]

Financial dependence puts local advocacy efforts at the mercy of funder changes to programmes. For example, in Ghana, Bloomberg added the issue of road traffic accidents to its tobacco control effort. In Tanzania, funders did not renew a grant after advocates were unable to get legislation passed in 2010. Short-term focus undermines local actors' ability to build the trust and legitimacy needed for policy implementation, ultimately limiting their effectiveness.[194]

Local advocates cannot easily turn to grantees above them in the tobacco control hierarchy to help them build capacity, because some of these actors (e.g. The Union and CTFK) also depend on Bloomberg or BMGF, making it hard for them to commit to long-term projects that do not show short-term results.

Worse still, one informant for this report said that where the WHO TFI, The Union and CTFK all have their own separate offices in one country managing different programmes, staff in these offices are known to deliberately hide activities from each other, leaving local grantees dancing from one higher-up grantee to the other in an atmosphere of mutual hostility, as funding and fiefdoms are protected.

> **Financial dependence puts local advocacy efforts at the mercy of funders' programmes, which undermines local ability to build trust and legitimacy.**
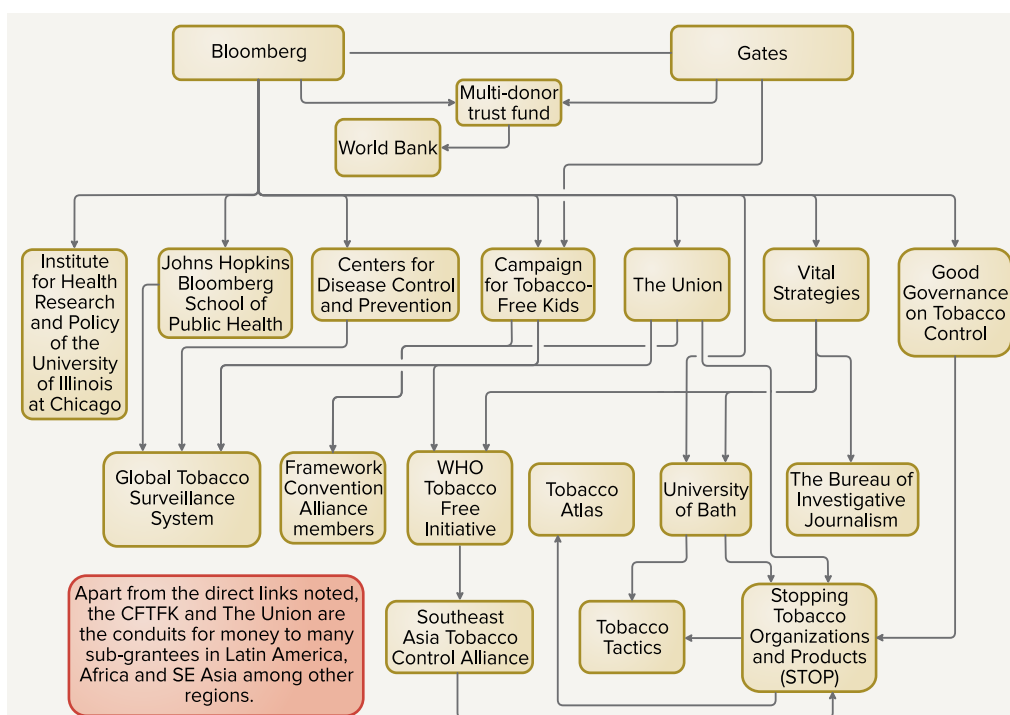
GSTHR 2020

This is a 'simplified' picture of the direction of the global funding streams, much of which appears devoted to action against THR. There will be many in-country local grantees and other organisations who also campaign against THR and who cite CFTK, Bloomberg and Gates as 'partners', without any clarity as to what this means.

The policies are as tangled as the personnel and the processes, so it is impossible to calculate how much of this substantial funding is now being directed against THR. But

[193] Patterson, A. S., & Gill, E. (2019). Up in smoke? Global tobacco control advocacy and local mobilization in Africa. *International Affairs*, 95(5), 1111–1130. https://doi.org/10.1093/ia/iiz102
[194] Patterson ibid.

at least from the perspective of public campaigning, positioning and in-country political lobbying, it must be considerable. It is equally impossible to know to what degree local grantees in the most affected countries genuinely sign up to the anti-THR war against nicotine agenda. However, as many in tobacco control – at whatever level in the funding firmament – approach these issues from a moral or even quasi-religious mindset, dissenting voices would be few. What is clear is that all the Bloomberg-funded agencies oppose THR when linked to the use of SNP.

Examples of anti-THR funding beneficiaries

The sums of money quoted are not a comprehensive accounting, but simply indicate the scale of the resources used to oppose tobacco harm reduction and SNP.

Campaign for Tobacco Free Kids (CTFK)

CTFK was established in 1995 by the Robert Wood Johnson Foundation (RWJF), the charitable arm of the pharmaceutical giant Johnson & Johnson, which sells NRT products. The arrival of SNP posed a direct threat to the pharmaceutical industry and multi-billion-dollar global sales of their NRT products. "The drugs industry is objecting to the marketing of e-cigarettes and vape pens as a way to quit cancer-causing cigarettes. Pharmaceutical companies…want e-cigarettes to be regulated as medical products…At stake: who will take the larger share of Europe's market for smoking cessation."[195]

An anti-smoking NGO was an ideal vehicle for Johnson & Johnson to push their NRT products under a cloak of charitable works. Both had an interest in stamping out SNP, providing an example of what economist Bruce Yadel dubbed an unlikely alliance of 'baptists and bootleggers'. In the run-up to Prohibition, both groups wanted legal alcohol banned for different reasons. For the Baptists it was a question of morality: for the bootleggers, it was money.

RWJF funded campaigns which promoted NRT included the Global Youth Action on Tobacco and the CHAMPSS campaign that focused on children helping parents to quit smoking. Since 1995, CTFK has received nearly $120m from pharmaceutical companies.[196]

Between 2011-2014, CTFK received over $30m from the Gates Foundation. Their annual reports over the last decade show income of around $150m, including donations from the main pharmaceutical companies selling NRT products: Johnson & Johnson, Pfizer and GlaxoSmithKline. CTFK receives major funding from BP, primarily to run overseas grants programmes, and also for anti-THR US campaign and lobbying work – including $160m specifically to orchestrate lobbying in pursuit of a ban on e-cigarette flavours.

The Union

Formerly the International Union against Tuberculosis and Lung Disease, founded in 1920, the Paris-based Union had a laudable track record in the international effort to combat TB. During the 1990s, its focus expanded to

> **Pharmaceutical companies… want e-cigarettes to be regulated as medical products… At stake: who will take the larger share of Europe's market for smoking cessation.**

195 Paun, C. (2019, June 24). *Big Pharma battles Big Tobacco over smokers*. POLITICO. https://www.politico.eu/article/big-pharma-battles-big-tobacco-over-smokers/

196 *Grants Explorer*. (2020). RWJF. https://www.rwjf.org/en/how-we-work/grants-explorer.html#k=tobacco-free%20kids&s=15

include tobacco control. It joined the army of those agencies campaigning against attempts to undermine tobacco control efforts, especially in LMIC. In step with other Bloomberg grantees, this has morphed into a general war against nicotine, particularly aimed at the advent of SNP. The Union also organises the World Conference on Tobacco or Health, which effectively bans anyone supporting THR not just from presenting, but even attending.

Recently, under the slogan, 'Bans are Best', the Union (and the CTFK) has been encouraging countries to introduce outright bans on all SNP on the basis of a hyper-inflated interpretation of the 'precautionary principle' (See Chapter 6).

Vital Strategies (VS)

Originally, VS was the World Lung Foundation, established as a US-based entity to allow American donors to claim tax relief. It operates globally in public health arenas such as air pollution, lead poisoning, obesity and cardiovascular health. It supports drugs harm reduction. Less beneficial to global public health is its weaponization of tobacco control to attack THR, through joint sub-funding programmes with The Union.

Tobacco Tactics (TT)

A direct Bloomberg grantee and a sub-grantee of both the Union and VS, who themselves are Bloomberg funded, TT is a database produced under the aegis of the Bath University Tobacco Control Research Group. It purports to be an academic resource and claims to be a 'new model of academic research dissemination'. It was established to track what in its view are examples of tobacco industry interference in tobacco control policies. It has been criticised for selective reporting and analysis. TT has consistently raised doubts about THR and the manufacturers of SNP. Its modus operandi includes ad hominem attacks against THR advocates.

Stop Tobacco Organisations and Products (STOP)

Also housed at Bath University and similarly funded, STOP uses TT information to be the public-face of FCTC Article 5.3 (see next chapter). STOP is often the vehicle for attacking THR researchers and advocates – usually, as with TT, by innuendo.

WHO Tobacco Free Initiative (TFI)

When the Bloomberg Initiative was launched, it was decided that the money should go to the WHO TFI, rather than being channelled through the FCTC Secretariat. The political context for this is the Americans' general dislike of international treaties, where they feel self-determination could be compromised by treaty obligations that might not be in US' best interests. In this case, while the US did not ratify the FCTC as signatories, they can attend the Conference of the Parties (COP) meetings, which they do in great numbers to keep an eye on what's going on. The FCTC Secretariat is hosted by the WHO in Geneva but is not directly answerable to the WHO, but to the Parties to the treaty. Direct funding to the FCTC Secretariat would mean Bloomberg would have less control over how the money was spent.

> **Recently, under the slogan, 'Bans are Best', the Union (and the CTFK) has been encouraging countries to introduce outright bans on all SNP on the basis of a hyper-inflated interpretation of the 'precautionary principle'.**

According to one informant, by the time the Bloomberg money began to flow, personal animosities between the then-respective organisational heads meant that there was already little love lost between the WHO TFI and the FCTC Secretariat – a situation that worsened over time. The FCTC Secretariat has to rely on voluntary contributions from the FCTC Parties, many of whom pay nothing. The Secretariat has petitioned the Parties to establish an investment fund. But the only countries likely to pay up are those who are already contributing – a tall order anyway, but in the light of COVID-19 and the world facing a global recession (if not depression), such a request is likely to prove a non-starter.

The key players in the Bloomberg sphere of influence refuse to acknowledge a role for THR in combatting the epidemic they have devoted their lives to defeating.

While the money made available for international tobacco control appears significant, it is very little when compared to the size of the problem. And for all the anti-tobacco activity undertaken across the world, it is clearly not enough. Therefore, it would have been hoped that all those agencies involved would embrace all the possible options to help reduce the smoking epidemic. Sadly, this is not the case. The key players in the Bloomberg sphere of influence refuse to acknowledge a role for THR in combatting the epidemic they have devoted their lives to defeating.

Dirty tricks

But anti-THR campaigning goes further than simply attacking THR. There is concerted effort to smear the reputations of individuals by allegations of industry influence. Simply citing industry influence – with no attempt to articulate whether that is true or how that influence might work – requires the least effort, while being the most damaging way to undermine research.

Direct attacks on individuals comes right out of the playbook of a pioneer of community activism: Saul Alinsky. Quoting Alinsky's 1971 book Rules for Radicals, former UK ASH director Mike Daube said, "rule one – personalize the problem – the people running these companies are responsible for these (smoking) deaths".[197]

The conflation of THR research with alleged industrial duplicity has given the green light to tobacco control activists to encourage conference organisers to withdraw speaking invitations – or even forbid attendance – to those who have been 'outed' in this way.

One of the most notorious recent examples of ad hominem attacks has been the treatment of Dr Marewa Glover from New Zealand. Dr Glover is an internationally-respected social scientist and campaigner for smokers within minority ethnic communities and their right to health through access to SNP. Claims that her work is influenced by the tobacco industry have seen her effectively barred from speaking and event sponsors pull out. She was also the subject of a failed whispering campaign to have her 2019 nomination for New Zealander of the Year withdrawn.

Smearing of this sort tends to be done through word of mouth, phone calls and so on with no evidence trail. However, Ashley Bloomfield, New Zealand's Director General of Health, wrote to all public and district health bosses,

[197] Berridge, V. (2013). *Demons: Our changing attitudes to alcohol, tobacco, and drugs.* Oxford University Press. P. 176

specifically telling them not to have anything to do with Dr Glover because some of her work had been funded by the Foundation for a Smoke-Free World. The letter did not offer any evidence as to how this funding might have influenced Dr Glover's work.

In a circulated New Zealand public heath newsletter, Dr Prudence Stone, CEO of the Public Health Association, claimed that Dr Glover had made false statements to the New Zealand parliamentary select committee considering amendments to the Smoke-free Environments (prohibiting smoking in motor vehicles carrying children) Amendment Bill. At least in this case, Dr Glover received a public apology, "Dr Stone and the PHA retract these comments and unreservedly apologise to Dr Glover for the comments made".[198]

Bad science

Researchers need their papers published, as career progression depends on it. Academic institutions need research published to justify grant payments. Most institutions have press officers who hope to attract media attention, so the temptation is to ramp up findings to make a good story.

The media has an unhealthy appetite for health scares, and pre-COVID-19, nothing whetted this appetite more than the 'dangers' of vaping. Often, researchers are quite circumspect in their conclusions and are uncomfortable when their press office over-egg the research pudding, resulting in sensationalised media reporting. However, in this case, there are vested interests in getting as much bad news out there as possible. Such interests are aided in this by the bias of some medical journals, while others have simply less-than-robust peer-review processes.

Richard Smith is the former editor of the British Medical Journal and on leaving his post wrote a refreshingly honest book entitled, *The Trouble With Medical Journals*. Commenting on the quality of much research that manages to get into print, often after multiple rejections, he quoted Drummond Rennie, deputy editor of the Journal of the American Medical Association who observed:

> *"There seems to be no study too fragmented, no hypothesis too trivial, no literature citation too biased or too egotistical, no design too warped, no methodology too bungled, no presentation of results too inaccurate, no analysis too self-serving, no argument too circular, no conclusions too trifling or too unjustified, and no grammar and syntax too offensive for a paper to end up in print."*[199]

There are numerous examples in the sphere of SNP research which come under the heading of 'How on earth did that get published?'. Broadly speaking, studies are deficient for a variety of reasons such as: laboratory studies with little relevance to the real world; lack of appropriate comparators; confusion of association with causation; inadequate conceptualisation and control of confounders; meta-analyses that rely on individually-flawed studies; and over-reaching policy conclusions bearing little relation to the research itself.

There are numerous examples in the sphere of SNP research which come under the heading of 'How on earth did that get published?'.

Readers are referred to the forensically clinical and scientific demolition of bad science to be found at the websites of Clive Bates, Professor Michael Siegel, Professor Brad Rodu, Dr Carl Philips and Dr Konstantinos Farsalinos, among others.[200]

[198] Dr Glover, personal communication.
[199] Smith, R. (2006). *The Trouble with Medical Journals* (1 edition). Routledge. P.85
[200] https://www.clivebates.com/; https://tobaccoanalysis.blogspot.com/; https://rodutobaccotruth.blogspot.com/; https://antithrlies.com/about/; http://www.ecigarette-research.org/research/

There are similarly flawed statements from government health representatives and medical and public health organisations. For example, the European Respiratory Association has a long anti-vaping track record. In 2019, it published a position paper in which it asserted that "based on scientifically-backed arguments (sic)…[a] tobacco harm reduction strategy should not be used as a population-based strategy in tobacco control" because THR is:

> "based on incorrect claims that smokers cannot or will not quit smoking; reliant upon undocumented assumptions that alternative nicotine delivery products are highly effective as a smoking cessation aid; built on incorrect assumptions that smokers will replace conventional cigarettes with alternative nicotine delivery products; ignorant to the lack of evidence to show that alternative nicotine delivery products are safe for human health".[201]

The statement earned a trenchant rebuttal in a letter from Professor John Britton at Nottingham University and several other signatories including Deborah Arnott, CEO of UK ASH. The letter – an exemplary response to common anti-THR claims – began:

> "The respiratory community is united in its desire to reduce and eliminate the harm caused by tobacco smoking, which is at present on course to kill one billion people in the 21st century. The stated policy of the European Respiratory Society is to strive 'constantly to promote strong and evidence-based policies to reduce the burden of tobacco related diseases'.

> "In our view, the recent ERS Tobacco Control Committee statement on tobacco harm reduction though well-intentioned, appears to be based on a number of false premises and draws its conclusions from a partial account of available data. It also presents a false dichotomy between the provision of 'conventional' tobacco control and harm reduction approaches. We therefore respond, in turn, to the seven arguments presented against the adoption of harm reduction in the Committee's statement."[202]

The WHO campaign against THR

Most damaging of all from a global public health perspective is the anti-THR attitude taken by the WHO.

Most damaging of all from a global public health perspective is the anti-THR attitude taken by the WHO. The WHO has made clear that recreational use of nicotine is unacceptable and through the auspices of the TFI and the FCTC, does all in its power to undermine THR.

In December 2019, giving evidence to the Philippine Senate Hearing on E-Cigarettes, Ranti Fayokun from the WHO HQ Department of Prevention of Non-Communicable Diseases claimed vaping products contain toxic and carcinogenic chemicals and metals, affect the developing brain, have caused EVALI since 2012 and led to cannabis use.

She would not answer the point that on the WHO's own International Agency on Research on Cancer (IARC) website, it had stated explicitly that:

> "Use of the e-cigarette does not involve burning of tobacco and inhalation of tobacco smoke as occurs in cigarette smoking; therefore the use of e-cigarettes is expected to have a lower risk of disease and death than tobacco smoking.

[201] *ERS Position Paper on Tobacco Harm Reduction. A statement by the ERS Tobacco Control Committee.* (2019, May). European Respiratory Society. https://www.ersnet.org/advocacy/eu-affairs/ers-position-paper-on-tobacco-harm-reduction-2019

[202] Britton, J. et al. (2020). A rational approach to e-cigarettes: challenging ERS policy on tobacco harm reduction. *European Respiratory Journal*, 55(5). https://doi.org/10.1183/13993003.00166-2020

Source: Wikimedia Commons
The World Health Organization, Geneva, Switzerland.

> *Introducing appropriate regulations will minimize any potential risks from e-cigarette use."*[203]

> *"E-cigarettes have the potential to reduce the enormous burden of disease and death caused by tobacco smoking if most smokers switch to e-cigarettes and public health concerns are properly addressed"*.

In January 2020, the WHO published a question and answer page on ENDS (Electronic Nicotine Delivery Systems). In response to severe criticisms, they published an unannounced update that removed some of the most obviously misleading statements, while making no acknowledgement of the corrections. To quote Clive Bates:

> *"There are nine questions and every single answer provides false, misleading or simplistic information,* and this remains true of the 29 January update. *It is a disgraceful travesty of science communication and policymaking advice and again puts in question the competence of the WHO – if there is still any doubt about this. But it is* so bad *that it even fails as anti-vaping activist propaganda – and* that *is a low bar"*.[204]

The uncompromisingly hostile approach to THR has to be set against a backdrop of tobacco control delivery which as one *Lancet* editorial observed has been 'staggeringly slow'.[205] Actors in the Bloomberg hierarchy are quick to blame the tobacco industry for slow progress. No doubt industry engagements with governments over the years have played their part. But there are many other factors to consider. These include: the poor uptake of tobacco control measures; that many countries with the worst smoking problems host a commercially important domestic tobacco industry, creating tensions between government departments dealing with business and (often politically weaker) health; and the fact that in countries with limited resources, immediate health issues might take priority over smoking, the deleterious effects of which take years to materialise.

The uncompromisingly hostile approach to THR has to be set against a backdrop of tobacco control delivery which as one *Lancet* editorial observed has been 'staggeringly slow'.

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[203] This statement has since been removed from the site
[204] For full details, see Bates, C. (2020, January 30). *World Health Organisation fails at science and fails at propaganda – the sad case of WHO's anti-vaping Q&A*. The Counterfactual. https://www.clivebates.com/world-health-organisation-fails-at-science-and-fails-at-propaganda-the-sad-case-of-whos-anti-vaping-qa/
[205] Lancet editorial 28th May 2016, p.2136

One study came to the startling conclusion that there was "no evidence to indicate that global progress in reducing cigarette consumption has been accelerated by the FCTC treaty mechanism."[206]

A Bloomberg presentation to grantees claimed that over five years, 14 million lives had been saved.[207] Yet, the only tools available to assess, for example, lives saved for non-smokers by introducing smoke-free environments are – at best – modelling and computer simulation techniques. As David Reubi notes, 'lives saved' data is beset with problems of overestimation, because of extrapolations, assumptions and generalisations.[208]

Having laws in place is deemed by the WHO, to be at the 'highest levels of achievement' – and many countries can only claim very modest progress. And without the means or the mechanisms for enforcement, these achievements are little more than window dressing.

Given the amounts of money being spent to enact the WHO MPOWER initiative globally, its limitations in actually reducing smoking and increasing lives saved are concerning. The steepest falls in smoking have been in high-income countries. These are states with relatively well-resourced health and social care systems, with substantial sectors of the population attuned to the benefits of a healthier lifestyle.

As the WHO admit, the weakest area of MPOWER achievement is O (offering help) – which is also the most expensive for any government, as it requires longer-term investment and infrastructure. But instead of opening up all the possibilities of 'offering help', including ready access to SNP, politicians and policymakers around the world are being encouraged by ostensibly trustworthy sources to take up arms in the war against nicotine.

[206] Hoffman, S. J. et al. (2019). Impact of the WHO Framework Convention on Tobacco Control on global cigarette consumption: quasi-experimental evaluations using interrupted time series analysis and in-sample forecast event modelling. *BMJ, 365*. https://doi.org/10.1136/bmj.l2287

[207] Reubi, op cit. p.97

[208] Reubi op cit. p.100

Chapter 6
The politics of health: SNP regulation and control

The arrival of SNP has caused disruption to the tobacco industry, to the certainties of decades-old tobacco research and to the uncontested 'heroes and villains' narrative of anti-tobacco campaigners. That uncertainty has also unnerved governments around the world left to play catch-up as to the most appropriate legislative responses.

Most countries have no specific legislation in place regarding SNP. In others, SNP have been folded into existing tobacco legislation, regulated as medicinal products or simply outlawed, leaving the most damaging combustible nicotine products legally available.

36 countries ban the sale of nicotine vaping products	Antigua and Barbuda, Argentina, Australia, Bhutan, Brazil, Brunei, Cambodia, Colombia, East Timor, Egypt, Ethiopia, Gambia, India, Iran, Japan, North Korea, Kuwait, Lebanon, Mauritius, Mexico, Nepal, Nicaragua, Oman, Panama, Qatar, Seychelles, Singapore, Sri Lanka, Suriname, Syria, Thailand, Turkey, Turkmenistan, Uganda, Uruguay, Venezuela
1 country bans the sale of tobacco*	Bhutan
75 countries regulate the sale of nicotine vaping products	Austria, Azerbaijan, Bahrain, Barbados, Belarus, Belgium, Bulgaria, Canada, Chile, China, Hong Kong, Costa Rica, Croatia, Cyprus, Czech Republic, Denmark, Ecuador, El Salvador, Estonia, Fiji, Finland, France, Georgia, Germany, Greece, Honduras, Hungary, Iceland, Indonesia, Ireland, Israel, Italy, Ivory Coast, Jamaica, Jordan, South Korea, Laos, Latvia, Liechtenstein, Lithuania, Luxembourg, Macedonia, Malaysia, Maldives, Malta, Moldova, Netherlands, New Zealand, Nigeria, Norway, Palau, Paraguay, Philippines, Poland, Portugal, Romania, San Marino, Saudi Arabia, Senegal, Serbia, Slovakia, Slovenia, South Africa, Spain, Sweden, Switzerland, Taiwan, Tajikistan, Togo, Tunisia, Ukraine, UAE, UK, US, Vietnam
85 countries have no specific laws or regulations on nicotine vaping products	Afghanistan, Albania, Algeria, Andorra, Angola, Armenia, Bahamas, Bangladesh, Belize, Benin, Bolivia, Bosnia and Herzegovina, Botswana, Burkina Faso, Burma (Myanmar), Burundi, Cameroon, Cape Verde, Central African Republic, Chad, Comoros, Congo, Democratic Republic of Congo, Cuba, Djibouti, Dominica, Dominican Republic, Equatorial Guinea, Eritrea, French Guiana, Gabon, Ghana, Grenada, Guatemala, Guinea, Guinea-Bissau, Guyana, Haiti, Iraq, Kazakhstan, Kenya, Kiribati, Kosovo, Kyrgyzstan, Lesotho, Liberia, Libya, Madagascar, Malawi, Mali, Mauritania, Monaco, Mongolia, Montenegro, Morocco, Mozambique, Namibia, Nauru, Niger, Pakistan, Palestine, Papua New Guinea, Peru, Russian Federation, Rwanda, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Samoa, Sao Tome and Principe, Sierra Leone, Solomon Islands, Somalia, South Sudan, Sudan, Swaziland, Tanzania, Tonga, Trinidad and Tobago, Tuvalu, Uzbekistan, Vanuatu, Yemen, Zambia, Zimbabwe

* Bhutan temporarily lifted the ban on tobacco sales from August 2020, the date of recommencement is uncertain.

Since our last report, the already-significant challenges of dealing with the global smoking epidemic have been further undermined by the increasingly prohibitionist approach and rhetoric of several countries, especially those in LMIC. Despite this, the number of countries with bans has decreased from 39 to 36 since our last report in 2018.

The number of countries which ban nicotine vaping products has decreased from

39 to **36**

since in 2018.

Changes in the legal status of nicotine vaping products between 29 September 2018 and 1 July 2020

From *banned* to *allowed*	Bahrain, Jordan, Malaysia, Saudi Arabia, UAE
From *no specific law* to *allowed*	Azerbaijan, Belarus, Chile, El Salvador, Georgia, Israel, Ivory Coast, Laos, Macedonia, Maldives, Senegal, Serbia, Switzerland, Tajikistan, Tunisia, Ukraine, Hong Kong
From *allowed* to *banned*	India, Kuwait, Turkey
From no *specific law* to *banned*	Iran

The number of countries in which HTP are marketed has increased from 2018 and they are now sold in 51 countries. The number of countries allowing the sale of snus has remained about the same since 2018.

51 countries where HTP are marketed	Andorra, Armenia, Austria, Bahrain, Bulgaria, Canada, Colombia, Croatia, Cyprus, Czech Republic, Denmark, Dominican Republic, Estonia, Ethiopia, France, Germany, Greece, Guatemala, Israel, Italy, Japan, Kazakhstan, Korea, South, Kuwait, Latvia, Lithuania, Macedonia, Malaysia, Moldova, Monaco, Netherlands, New Zealand, Oman, Palestine, Poland, Portugal, Qatar, Romania, Russian Federation, Saudi Arabia, Serbia, Slovakia, Slovenia, South Africa, Spain, Switzerland, Taiwan, Ukraine, UAE, UK, US
13 countries ban the sale of HTP	Australia, Ethiopia, India, Iran, Malta, Norway, Panama, Singapore, Sri Lanka, Thailand, Turkey, Turkmenistan, Mexico (ban on sale and import of tobacco heating device only – HTP consumables are considered tobacco products regulated by the existing Tobacco Law).
81 countries allow the sale of snus	Afghanistan, Albania, Algeria, Angola, Argentina, Armenia, Bahamas, Bangladesh, Barbados, Bolivia, Bosnia and Herzegovina, Botswana, Canada, Chile, China, Hong Kong, Colombia, Costa Rica, Dominican Republic, Egypt, El Salvador, Ethiopia, Gabon, Gambia, Georgia, Ghana, Guatemala, Guinea, Honduras, Israel, Ivory Coast, Japan, Kazakhstan, Kenya, Korea, South, Kosovo, Kuwait, Kyrgyzstan, Lebanon, Lesotho, Liberia, Libya, Malaysia, Mali, Mauritania, Mauritius, Mexico, Mongolia, Morocco, Mozambique, Namibia, Nepal, Nicaragua, Niger, Norway, Oman, Palestine, Panama, Paraguay, Peru, Philippines, Qatar, Saudi Arabia, Senegal, Sierra Leone, Somalia, South Africa, Swaziland, Sweden, Switzerland, Syria, Taiwan, Thailand, Trinidad and Tobago, Tunisia, Ukraine, UAE, US, Uruguay, Uzbekistan, Venezuela
39 countries ban the sale of snus	Australia, Austria, Bahrain, Belarus, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Macedonia, Malta, Montenegro, Netherlands, New Zealand, Poland, Portugal, Romania, Russian Federation, Slovakia, Slovenia, Spain, Turkey, Turkmenistan, UK, Vanuatu

For country specific detail, see the GSTHR website www.gsthr.org.

Tobacco control regulation is enacted at international, regional and national level. Within countries with semi-autonomous federations and states, such as the US, Canada and Australia, slightly different rules and regulations apply between individual jurisdictions and between jurisdictions and the central government.

WHO FCTC and the Conference of the Parties (COP)

The Framework Convention on Tobacco Control (FCTC) was the world's first WHO international health treaty and came into force in 2005, setting a framework for countries to construct their own tobacco control policies, particularly those LMIC who do not have the necessary resources to formulate their own policies from scratch. It is generally accepted that there needs to be regulations to control the sale and marketing of cigarettes, the places where people can smoke and access to cigarettes by young people. The problems with the implementation of the FCTC and its guidelines arise from the arrival of the newer SNP which came onto the market after 2005.

Funding from Bloomberg has enabled the CTFK to expand its role internationally – for example, by advising LMIC on SNP controls. The CTFK knows that many countries do not have specific regulations about SNP. They also know that many countries have not fully implemented the FCTC and may not do so in the foreseeable future. Their advice (and that of The Union[209] and the WHO TFI) is for countries to totally ban SNP until or unless they have fully implemented the Convention, and then to regulate SNP as if they were combustible products. Current smokers in those countries who follow this advice may have limited chances of legal access to SNP.[210]

> The newer SNP came onto the market after the FCTC came into force in 2005.

The Union — International Union Against Tuberculosis and Lung Disease — Health solutions for the poor — THEUNION.ORG

WHERE BANS ARE BEST

WHY LMICs MUST PROHIBIT E-CIGARETTE AND HTP SALES TO TRULY TACKLE TOBACCO

2020 UPDATED POSITION PAPER

Union Position Paper on E-cigarettes and HTP sales in LMICs. (n.d.). The Union. Retrieved 20 July 2020, from https://www.theunion.org/what-we-do/publications/technical/union-position-paper-e-cigarette-and-htp-2020

In what might be described as neo-colonialism, CTFK and other influential NGOs have a track record of interfering in signatory countries' business, going back to the negotiations leading up to the introduction of the FCTC.

Greg Jacob was a constitutional law expert at the UN Department of Justice Office of Legal Counsel and a member of the US delegation involved in the final stages of the FCTC negotiations in Geneva during 2003. The following year, he published an article in the Chicago Journal of International Law in which he slammed the FCTC negotiations as a "train wreck" and a "deeply flawed process".[211]

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[209] *Union Position Paper on E-cigarettes and HTP sales in LMICs.* (n.d.). The Union. Retrieved 20 July 2020, from https://www.theunion.org/what-we-do/publications/technical/union-position-paper-e-cigarette-and-htp-2020
[210] CTFK webinar on control of SNP https://www.youtube.com/watch?v=9RczYcBZkyY&feature=youtu.be&t=319
[211] Jacob, G. (2004). Without Reservation. *Chicago Journal of International Law,* 5(1). https://chicagounbound.uchicago.edu/cjil/vol5/iss1/19, p.287-302

As this was the first time the WHO had been involved in drafting an international health treaty, many of the delegates were health minsters, several of whom were doctors. But while they knew much about the health effects of smoking, they knew nothing about international law and the process of treaty negotiations – neither, incidentally, did WHO officials. Into the breach, wrote Jacob, came US NGOs, primarily ASH and CTFK, who banded together to form the Framework Convention Alliance (FCA) of WHO-'approved' anti-tobacco NGOs. He described how this influence played out:

> "...the NGOs certainly did not act as disinterested legal advisers, and along the way more than one delegation was hoodwinked into believing the NGOs' all-too-frequently distorted versions of the truth."

Nor were they above believing, like all moral entrepreneurs, that the ends justified the means; Jacobs said he was followed all over the building by NGO representatives trying to listen in on his phone calls and taking notes.

There was another aspect to the negotiations which disturbed Jacob, and whose impact is keenly felt today. Concerning the definition of "tobacco advertising and promotion", it was clear to Jacob and most of the delegates in negotiating meetings that the definitions were ridiculously broad.

> "It took a minor miracle just to get the word 'commercial' inserted into the definition of 'tobacco advertising and promotion', as many members of the [WHO regional groups] wanted the definition to cover non-commercial speech by actors outside the tobacco industry."

To this day, interference is continuing with increasing ferocity in the attempt to 'no-platform' anybody who advocates or researches THR, who in this narrative is, by definition, an industry 'insider'. What has become a tobacco control obsession and a major distraction from the real (and far more complex and challenging) issue of reducing smoking-related death and disease is enshrined in an obscure document – the Guidelines to treaty Article 5.3.

The Article itself reasonably exhorts parties to the treaty to be open and transparent in their dealings with the tobacco industry and not allow undue interference in policy. The Guidelines which accompany the main text however have been ludicrously over-interpreted, as shown by this recent example.

The Bloomberg-funded STOP campaign, linked to the Good Governance of Tobacco Control and the South East Asian Tobacco Control Alliance agencies, recently launched a competition for under-18 year-olds to design graphics aimed at raising awareness, with an all expenses trip to Bangkok for the winners.[212] This was the Declaration of Interest Statement to which entrants were asked to agree:

Declaration of Interests

A. "INTERESTS" REFER TO ANY FINANCIAL OR NON-FINANCIAL LINKS WITH THE TOBACCO INDUSTRY, INCLUDING THROUGH EMPLOYMENT, CONSULTANCY, RESEARCH, BUSINESS, PROFESSIONAL OR PERSONAL INTERESTS, CONTRIBUTIONS OR GIFTS, FAMILY'S OR SPOUSE/PARTNER'S INTERESTS, RELATIONSHIPS UP TO THE FOURTH DEGREE OF CONSANGUINITY AND AFFINITY, AND FREQUENT OR REGULAR SOCIAL RELATIONSHIPS. (REFER TO ANNEXED CHART OF RELATIVES FOR CLARITY.)

B. "TOBACCO INDUSTRY" REFERS TO (A) ANY TOBACCO OR TOBACCO PRODUCT MANUFACTURER, PROCESSOR, WHOLESALE DISTRIBUTOR, IMPORTER , (B) ANY PARENT, AFFILIATE, BRANCH, OR SUBSIDIARY OF A TOBACCO OR TOBACCO PRODUCT MANUFACTURER, WHOLESALE DISTRIBUTOR, IMPORTER, RETAILER, OR (C) ANY INDIVIDUAL OR ENTITY, SUCH AS, BUT NOT LIMITED TO AN INTEREST GROUP, THINK TANK, ADVOCACY ORGANIZATION, LAWYER, LAW FIRM, SCIENTIST, LOBBYIST, PUBLIC RELATIONS, AND/OR ADVERTISING AGENCY, BUSINESS, OR FOUNDATION, THAT REPRESENTS OR WORKS TO PROMOTE THE INTERESTS OF THE TOBACCO INDUSTRY, INCLUDING, BUT NOT LIMITED TO THOSE LISTED IN TOBACCOTACTICS.ORG.

I DECLARE THAT, OTHER THAN THE INTERESTS DECLARED IN THE FORM BELOW, I DO NOT HAVE INTERESTS, CURRENTLY OR IN THE PAST FIVE (5) YEARS, RELATED TO THE TOBACCO INDUSTRY, AND I AM NOT KNOWINGLY REPRESENTING OR RECEIVING ANY CONTRIBUTION OR COMPENSATION, DIRECTLY OR INDIRECTLY, WHETHER FINANCIAL OR OTHERWISE, FROM THE TOBACCO INDUSTRY.

I CERTIFY THAT THE INFORMATION GIVEN ABOVE IS, TO THE BEST OF MY KNOWLEDGE, TRUE, ACCURATE, AND COMPLETE.

That phrase "the fourth degree of consanguinity" means the entrant – a teenager – has to assert no industry connections going back to their great great grandparents – or to third cousins three times removed.

Yet while the concept of THR is shunned by the WHO and all Bloomberg-funded agencies, Article 1 paragraph (d) on page 11 of the FCTC specifically says that, "'tobacco control' means a range of supply, demand and *harm reduction* [emphasis added] strategies that aim to improve the health of a population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke." There were no vaping products in general circulation at the time the FCTC was drawn up, but by then the WHO had recognised the public health imperative in relation to HIV and drugs and knew what harm reduction meant in those circumstances. Once SNP became widely available, there was plenty of opportunity for WHO to offer an actual definition of harm reduction through guidance in line with its application to other global health issues.

SNP (or ENDS in WHO terminology) only came onto the agency's radar about ten years ago. The COP meeting of FCTC signatory countries is held every two years. At both COP 4 (2010) and COP 5 (2012) there were some early discussions about how the new products might be regulated. At the COP 6 meeting, the WHO were asked to prepare a briefing paper for COP 7, which was delegated to the WHO Study Group on Tobacco Product Regulation (TobRegNet).

The TobRegNet report was relatively balanced. For example, paragraph 5 on the potential role of SNP in tobacco control states:

> "If the great majority of tobacco smokers who are unable or unwilling to quit would switch without delay to using an alternative source of nicotine with lower health risks, and eventually stop using it, this would represent a significant contemporary public health achievement."[213]

Delegates to COP7 welcomed the report and the Parties went away to consider applying regulatory measures *as appropriate to their national laws and public health objectives*. This is an important point – and a feature of all UN multilateral treaties. While the FCTC is 'legally binding', all this means in practice is that Parties have signed up to enacting controls in the spirit of custom and practice as applied to all international treaties. But aside from smuggling, tobacco control is an issue for domestic law and ultimately what passes into law remains in the gift of individual governments.

TobRegNet produced another report in 2019; it too is a reasonably balanced evidence review.[214] The report refers to a much-abused concept known as the precautionary principle – meaning a cautious approach to potentially harmful innovations. In 2000, the EU Commission produced detailed guidance on achieving the balance in policymaking between rights and freedoms against reducing risks, whether to humans, animals, or the environment. The guidelines encourage political decisions to be taken for example, on the basis of proportionality, non-discrimination, a cost/benefit analysis and specifically on "examination of scientific developments".

The precautionary principle has been over-interpreted at an FCTC political level to push for maximum controls – just to be on the 'safe side'. However, there is nothing

[212] *Expose Tobacco Industry Manipulation, Save the Next Generation*. (2020). https://www.ggtc.world/exposetobacco/

[213] *Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems* (ENDS/ENNDS). (2016). [Statement]. WHO. https://www.who.int/fctc/cop/cop7/FCTC_COP_7_11_EN.pdf

[214] *WHO Study Group on Tobacco Product Regulation. Report on the scientific basis of tobacco product regulation: seventh report of a WHO study group*. (No. 1015; WHO Technical Report Series). (2019). World Health Organization. https://apps.who.int/iris/bitstream/handle/10665/329445/9789241210249-eng.pdf

in the latest TobRegNet report which could be taken as a signal to FCTC parties to ramp up an increasingly prohibitionist approach to SNP. Nevertheless, there is now a widening disconnect between the tone of the scientific evidence produced within the WHO and its public-facing political rhetoric attacking THR.

In September 2019, Dr Vera Luiza da Costa e Silva, then Head of the Convention Secretariat, claimed, "Vaping is a treacherous and flavored camouflage of a health disaster yet to happen if no action is taken now''.[215]

Her successor, Dr Adriana Marquizo, from Uruguay (which has already banned SNP yet is the first country in the world to legalise marijuana) stuck to the party line in this interview:

> *"This is an area that is very worrying, especially because of the systematic, aggressive and sustained marketing tactics employed to attract a new generation of tobacco users, through the introduction of flavours and other attractive features."*[216,217]

European Tobacco Products Directive (TPD)

https://commons.wikimedia.org/wiki/File:European_Commission_in_Brussels.jpg

Passed in 2001, the Tobacco Products Directive (TPD) was the first major European legislation specifically related to tobacco products. It is the only example of a regional approach to regulation. All EU member states must implement TPD into national legislation.

215   *WHO | The Convention Secretariat calls Parties to remain vigilant towards novel and emerging nicotine and tobacco products.* (n.d.). WHO; World Health Organization. Retrieved 1 July 2020, from http://www.who.int/fctc/mediacentre/ news/2019/remain-vigilant-towards-novel-new-nicotine-tobacco-products/en/

216   *WHO FCTC.* (2020, June 15). https://www.facebook.com/FCTCofficial/posts/2578089132443187

217   Just to reiterate, while the WHO plays host to the FCTC Secretariat and is the legal employer of staff, the Secretariat is technically independent of both the WHO and its tobacco control programme and answerable instead to the signatory countries to the FCTC.

Nearly a decade before, the first attack on what turned out to be a significant SNP was the EU-wide ban on the sale of snus in 1992, as a response to the attempt by the US Smokeless Tobacco Company to introduce oral Skoal Bandits into the UK. When Sweden joined the EU in 1995, snus was already in widespread use there and so was exempted from the ban.

Legal status of snus

GSTHR 2020
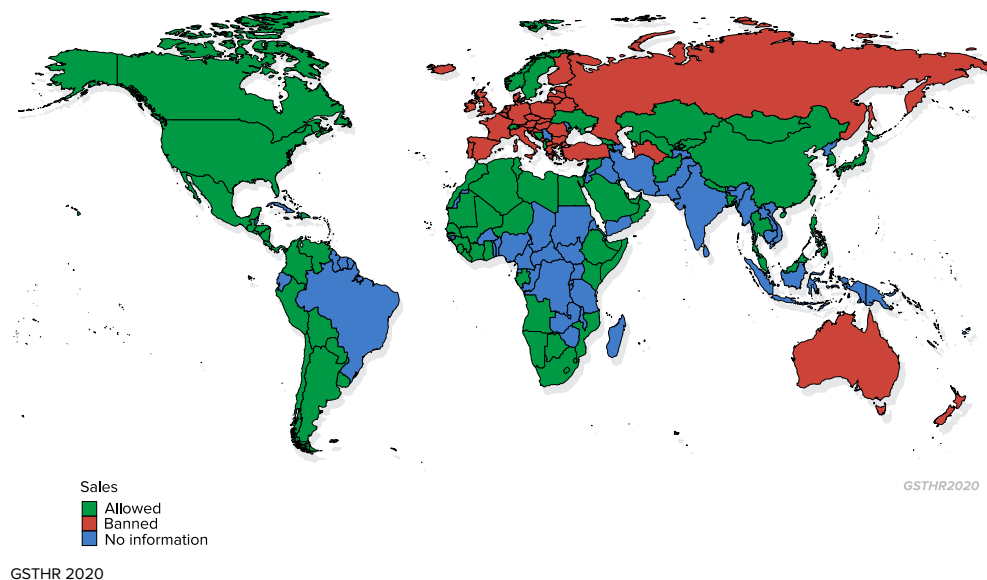
In the years subsequent to TPD enactment, EU Commission reports identified new tobacco-related products which might be controlled to ensure conformity with EU harmonisation policies, noting increasing discrepancies between member states. As the sale of vaping devices was growing throughout the EU, member states were seeking advice and clarification from the Commission. In 2012, the Health and Consumer Directorate produced a proposal for the revision of the 2001 TPD whereby products with a nicotine content over a certain level – including most vaping products on the market – would have to be authorised as medicines.

When the proposal came before the EU Parliament in 2013, numerous amendments to the Article were proposed, including one that all vaping products could only be sold as medicines under pharmaceutical regulations. Major objections from vapers via their EU political representatives helped derail this idea. In 2016, a revised TPD known as TPD2 came into force.

TPD2 regulates tobacco product manufacture, sale, distribution and advertising in the European Union covering vaping and HTP – with limitations on nicotine content and liquid bottle size – while reaffirming the ban on snus. Currently TPD2 is under review, with the report and possible proposals due out in May 2021.

In preparation for the next iteration of the TPD, input has been requested from the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER).

In 2018, the EU Agency Network for Scientific Advice (ANSA) published a report looking at how EU agencies approached the issue of scientific uncertainty in their different spheres of expertise.

The report concluded that across the 12 EU agencies in the network, there were inevitable differences as to what constituted scientific uncertainty, depending on the type of data being used for scientific assessment – for example, the difference between clinical or toxicological datasets as opposed to social science population studies. Even so, agencies need to find a balance when communicating 'truthful'

uncertainties without risking a fixed interpretation of 'nothing is known'. "Finding this balance is a primary focus of risk communication and is of fundamental importance in all Agencies."[218]

So it is a concern that SCHEER finds the right balance in presenting their opinion using all the available evidence of what is known, while not over-interpreting the precautionary principle, although the terms of reference for opinion are weighted towards risks rather than benefits:

> *"The assessment will address the role of vaping devices, in relation to:*
> *– their use and adverse health effects (i.e. short- and long-term effects)*
> *– risks associated with their technical design and chemical composition (e.g. number and levels of toxicants) and with the existing EU regulatory framework (e.g. nicotine concentration and limits)*
> *– their role as a gateway to smoking/the initiation of smoking (particularly focusing on young people)*
> *– their role in cessation of traditional tobacco smoking."*

The Commission is also seeking input from the research company Open Evidence which, in consortium with the London School of Economics, BDI Research and the Catalan Institute of Oncology, will conduct a product perception study. The consortium will look into:

> *"Consumer preference and perception of specific categories of tobacco and related products for the European Commission (DG SANTE). The study wants to analyse the consumer preferences and perceptions of consumers on 5 tobacco product categories, namely: novel tobacco products, small cigarillos, slim cigarettes, electronic cigarettes, waterpipe tobacco.*

> *"The study will summarise the information available to date and collect quantitative and qualitative primary data to provide a holistic view of those products and their consumers"*[219]

Scientific inputs into policymaking are often quite cautious and liberally sprinkled with caveat. The degree to which the EU Commission and member states over-interpret or cherry pick the evidence remains to be seen. But already public statements like this do not bode well:

> *"'E-cigarettes may be less harmful, according to some reports, but they're still 'poison',' said Arūnas Vinčiūnas, head of cabinet of EU Health [Commission]."* (EURACTIV, Feb 6, 2019).

Vinčiūnas followed up with:

> *"I am particularly concerned about young people taking up vaping and various new products like heated tobacco products and e-cigarettes, which are increasingly being marketed with misleading claims."* (World No Tobacco Day, 29 May 2019).

Thus the 'mood music' on the future for SNP within the EU is not promising. With SNP already allowed and established within the EU, it is unlikely that the review will recommend a complete ban, although there is no political interest in reversing the

[218] *European Food Safety Authority. (2018). Approaches to assess and manage scientific uncertainty: examples from EU ANSA agencies.* (Publications Office of the European Union, pp. 33–34) [Research policy and organisation]. Publications Office of the European Union. http://op.europa.eu/en/publication-detail/-/publication/9880c8bc-83eb-11e8-ac6a-01aa75ed71a1

[219] *Information webinar on tobacco policy. Videoconference. Draft summary record.* (2020, March 19). https://ec.europa.eu/health/sites/health/files/tobacco/docs/ev_20200319_sr_en.pdf

ban on snus. However, the banning of flavours would be a de facto ban, which would discourage smokers looking to switch away. Flavour bans are gaining popularity as a way of undermining THR. The Netherlands has already proposed a domestic Dutch flavour ban while Denmark and Belgium have signalled a similar approach. Control of flavours could well be the next global battleground in defence of THR.

It is possible there is some political push-back among FCTC signatories against complete bans, as this, in theory, would require a level of enforcement priority that might be felt to be an imposition – especially in LMIC with limited capacities and other public health priorities. However, flavour bans (and only allowing sales for medically-approved products) could effectively kill off much of the SNP industry, while ticking political boxes showing governments were 'doing something'.

**Control of flavours could well be the next global battleground in defence of THR.**

At the Eighth European Conference on Tobacco or Health, held in Berlin in February 2020, DG SANTE, responsible for the EU Commission's Health and Food Safety policies, recommended just such a ban. A declaration emerging from the conference urged the equalisation of tax regimes for vaping and tobacco. This could put vaping products out of the reach of many users, and could force existing users back to cheaper cigarettes – especially products derived from illegal markets.

All the indications are that the FCTC Secretariat will be pushing a prohibitionist line at the next COP and will no doubt be influenced by the outcome of the TPD review, not least because both processes share officials, highlighting the inter-connectivity and influence of one on the other. The next COP meeting will be held in the Netherlands in November 2021, six months after the report on the review of TPD 2, having been delayed for 12 months due to the COVID pandemic.

SNP: a global and national overview

Legal status of nicotine vaping products

Sales
- Allowed
- Banned
- No information

GSTHR2020

GSTHR 2020
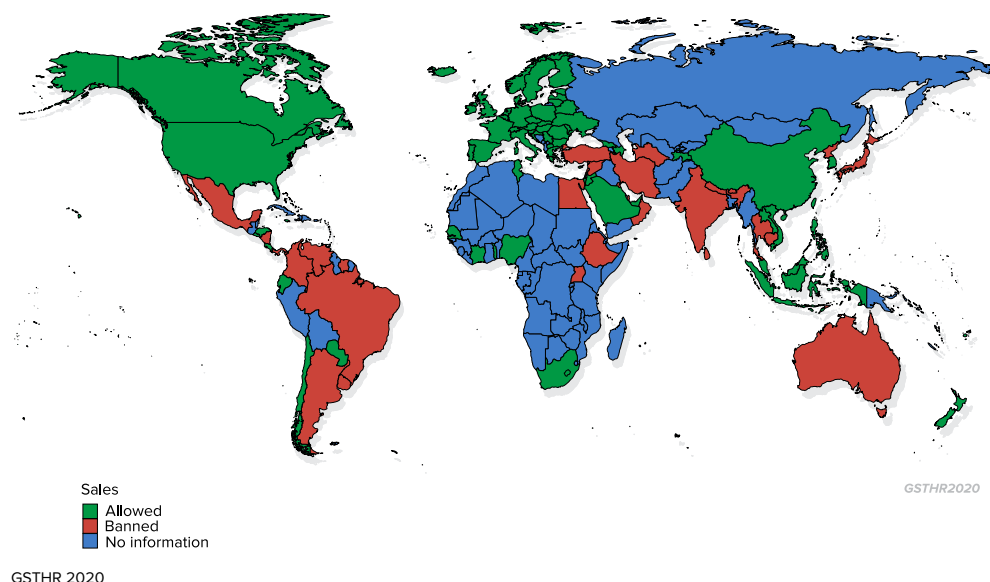
Beyond the big picture there is a whole panoply of regulatory options covering product registration, safety and limitations (such as nicotine content, and flavour bans), taxation levels, online sales, age-purchase limitations and public space vaping. For country specific detail, see the GSTHR website www.gsthr.org.

64 countries have age restrictions on the sale of nicotine vaping products	16+: Austria, Belgium, Liechtenstein 118+: Barbados, Bhutan, Brazil, Bulgaria, China, Hong Kong, Costa Rica, Croatia, Cyprus, Czech Republic, Denmark, Ecuador, El Salvador, Estonia, Fiji, Finland, France, Georgia, Germany, Greece, Hungary, India, Ireland, Israel, Italy, Ivory Coast, Latvia, Lithuania, Luxembourg, Malaysia, Maldives, Malta, Mexico, Moldova, New Zealand, Netherlands, Norway, Poland, Portugal, Romania, San Marino, Senegal, Slovakia, Slovenia, South Africa, Spain, Sweden, Tajikistan, Togo, UAE, UK, US, Vietnam 19+: Canada, South Korea, Turkey 20+: Japan 21+: Ethiopia, Honduras, Palau, Philippines
71 countries regulate the advertising of e-cigarettes	**34 (allowed at point of sale)** Austria, Barbados, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, El Salvador, Estonia, Fiji, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Saudi Arabia, Serbia, Slovakia, Slovenia, Spain, Sweden, UK, Ukraine **59 (not allowed in mass media)** Antigua and Barbuda, Argentina, Australia, Bahrain, Belarus, Belgium, Brazil, Bulgaria, Colombia, Costa Rica, Croatia, Denmark, East Timor, Ecuador, Estonia, Ethiopia, Fiji, Finland, France, Gambia, Georgia, Germany, Greece, Honduras, India, Iran, Ireland, Israel, Italy, Ivory Coast, Jordan, Latvia, Lithuania, Luxembourg, Maldives, Malta, Mexico, Nepal, Netherlands, New Zealand, Norway, Palau, Panama, Poland, Portugal, Romania, San Marino, Saudi Arabia, Senegal, Serbia, Slovakia, Slovenia, South Africa, Sweden, Togo, Turkey, Turkmenistan, UK, Vietnam **26 (bans on all advertising)** Antigua and Barbuda, Australia, Bahrain, Belarus, Colombia, Costa Rica, East Timor, Ecuador, Ethiopia, Gambia, Georgia, Honduras, India, Israel, Ivory Coast, Jordan, Maldives, Nepal, Norway, Palau, Panama, Senegal, South Africa, Togo, Turkmenistan, Vietnam
30 countries tax vaping liquid	**USA:** As of December 31, 2019, 20 states (California, Connecticut, Delaware, Illinois, Kansas, Louisiana, Maine, Massachusetts, Minnesota, Nevada, New Jersey, New Mexico, New York, North Carolina, Ohio, Pennsylvania, Vermont, Washington, West Virginia and Wisconsin), the District of Columbia, Puerto Rico and the US Virgin Islands have passed legislation that requires a tax on e-cigarettes. Eleven states (Connecticut, Delaware, Kansas, Louisiana, New Jersey, New Mexico, North Carolina, Ohio, Washington, West Virginia, and Wisconsin) tax e-cigarettes per millilitre of liquid or consumable material. California, Illinois, Maine, Massachusetts, Minnesota, Nevada, New Mexico, New York, Pennsylvania, Vermont, the District of Columbia, and the US Virgin Islands tax e-cigarettes on a percentage of a specified cost. Puerto Rico taxes the e-cigarette device themselves if disposable, and the nicotine cartridge per ml of consumable liquid.[220] **European region:** Excise per 1 ml of the e-cigarette liquid in Euro: Albania: 0.08, Azerbaijan: 1.1, Croatia: 0, Cyprus: 0.12, Estonia: 0.2, Finland: 0.3, Georgia: 6.6, Greece: 0.1, Hungary: 0.17, Italy: 0.08, Korea, South: 1.41, Latvia: 0.01, Lithuania: 0.12, Montenegro: 0.9, Poland: 0, Portugal: 0.3, Romania: 0.11, Russian Federation: 0.164, Serbia: 3.59, Slovenia: 0.18, Sweden: 0.19 **Asia-Pacific:** Indonesia: yes, but unknown. Philippines: The tax rates for freebase e-liquids have been set at 45 per cent in 2020 rising to 60 per cent in 2023. For nicotine salts, tax rates rise from 37 per cent in 2020 to 52 per cent in 2023.

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220 *STATE System E-Cigarette Fact Sheet.* (2020, March 18). https://www.cdc.gov/statesystem/factsheets/ecigarette/ECigarette.html

Middle-East
Jordan: 200% on the CIF (Cost, Insurance and Freight) value of nicotine containing liquid. A similar tax falls on the CIF value of e-cigarette devices.
Saudi Arabia: 100%. The General Authority of Zakat and Tax announced that it would expand the group of products subject to a 100% excise tax to include e-cigarette in an effort to boost non-oil revenues.
Bahrain in July 2018 classified e-liquids as tobacco products and therefore subject to the 100% tax on CIF value.
UAE: 100% (rates will start taxing vaping devices and e-cigarette at 100% starting in January 2020.

Africa
Kenya: 3,000 KES (=30USD) per 1 e-cigarette and 2,500 KES per cartridge for use in electronic cigarettes.

For country specific detail, see the GSTHR website www.gsthr.org.

North America

US

https://www.flickr.com/photos/fdaphotos/5205198800/in/album-72157625222669029

What happens in the US tends to be a beacon for legislators in other parts of the world.

In 2009, under the Family Smoking Prevention and Tobacco Control Act, the FDA was granted the legislative power to regulate tobacco products and marketing for cigarettes, loose tobacco for self-rolling and smokeless products. This was extended in 2016 to include cigars, pipe tobacco, water pipes and all vaping devices.

At that point, the FDA deemed that any product not on the market before 2007 had to go through a Pre-Market Tobacco Application (PMTA). The initial deadline for

non-combustible products was August 2021. A legal bid by anti-vaping organisations brought this forward to May 2020 – a date that was further revised due to COVID-19, ending up as the 9 September 2020. To make health comparisons for these products with smoking, a Modified Risk Tobacco Product Application (MRTPA) would also be required. This of course captured every type of vaping device on sale in the country. Small companies struggled to meet the onerous costs of compliance.

However, in October 2019, and in a ground-breaking move, the FDA authorised the marketing of eight Swedish Match snus products as modified risk tobacco products (MRTP). This allows the products to be marketed to consumers with the information that using the products put the user at lower risk of "mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis" compared to smoking.[221] In July 2020, the MRTP authorisation was granted to IQOS, allowing the promotion of the product as putting the consumer at lower risk than smoking. These FDA authorisations represent the first time any government has allowed the marketing of specific SNP as of lower risk than smoking.

The 2009 Act allowed state and local authorities to enact legislation in addition to, or more stringent than the Act, and since then several states have enacted variations on a theme around bans, taxation, purchase age restrictions and other regulations. Attention also focused on flavoured e-liquid which anti-vaping campaigners claim were developed deliberately to attract young people.

As far back as 2017, elected officials in San Francisco passed a flavour ban on all tobacco and nicotine products, which was later approved by voters in 2018. In June 2019, San Francisco took the additional step of banning the manufacture, distribution and sale of vaping products until they received FDA authorisation. In February 2020, a bill was passed through the US House of Representatives which would ban the sale of flavoured e-liquid and other flavoured tobacco products such as menthol cigarettes nationwide, and impose new restrictions on the marketing of vaping products. However, the Trump Administration refused to back the bill, on the basis that it "contains provisions that are unsupported by the available evidence regarding harm reduction and American tobacco use habits" and that, furthermore, the Bill "may restrict access by adult e-cigarette users to products that may provide a less harmful alternative to traditional cigarettes".[222]

In September 2019, the media storm over JUUL use and lung injuries and deaths prompted the governor of Michigan to institute a temporary ban on flavoured e-liquid. Soon after, President Trump suddenly announced a proposed nationwide ban on all flavoured vape liquids sold without FDA authorisation. While other states like New York, Oregon and Washington followed with their own temporary bans (some eventually made permanent), President Trump and the FDA rethought their plan as evidence accumulated that illicit THC cartridges had been cause of injuries and deaths. In early January 2020, however, the FDA announced plans to temporarily ban flavoured pods except for menthol and tobacco flavours, while excluding the bottled e-liquids used in refillable tank systems largely favoured by regular adult consumers.

At various points over the past few years, FDA officials have made encouraging noises about tobacco harm reduction. Unfortunately, in the white heat of political and media pressure, these pronouncements have often been followed by proposals diametrically opposed to the best interests of smokers.

> These FDA authorisations represent the first time any government has allowed snus or heated tobacco products to be marketed to consumers as less risky than smoking tobacco.

221 Office of the Commissioner. (2020, March 24). *FDA grants first-ever modified risk orders to eight smokeless tobacco products*. FDA. https://www.fda.gov/news-events/press-announcements/fda-grants-first-ever-modified-risk-orders-eight-smokeless-tobacco-products
222 Associated Press. (2020, February 28). *House passes bill to ban the sale of flavored e-cigarettes and tobacco products*. NBC News. https://www.nbcnews.com/politics/politics-news/house-passes-bill-ban-sale-flavored-e-cigarettes-n1145186

https://commons.wikimedia.org/wiki/File:Vape_Juice_(24380470373).jpg

We outlined the FDA structures and approval processes in our 2018 report. The overall view, from market and policy analysts, was that the process for obtaining market approvals for SNP – substantial amounts of time and money to deliver proposals running into thousands of pages – would most likely be beyond the resources of all but the major tobacco companies. The independent SNP market in the US could be wiped out.

Canada

Until 2018, Canadian federal health officials had based their approach to vaping on existing laws on nicotine products which in effect made vaping products illegal. This was largely ignored by vapers and their suppliers, and there was little enforcement intervention. Then in May 2018, the Tobacco and Vaping Products Act was introduced. The Act legalised vaping and the vaping industry, allowing SNP to be sold in convenience stores and gas stations as well as vape shops. Generally, the legislation takes a relatively sensible approach to SNP; it also covers HTP, which are regarded as tobacco products. The Act is geared towards protection of young people. This means, for example, that any attempt to promote products to smokers as safer nicotine options is banned unless products receive pre-market approval under the Food and Drug Act.

However, at the time of writing, the Federal government is moving towards a more prohibitionist approach. Canadian provinces have already moved to enact more restrictive regulations; for example, Nova Scotia has capped the nicotine level per bottle of e-liquid to 20mg/ml and banned the sale of flavours, while Ontario has restricted sales of higher than 20mg/ml strengths and most flavours to vape shops only. Prince Edward Island banned sales other than in vape shops. British Columbia, Nova Scotia and Alberta are implementing a special tax on vaping products.[223] However, in Canada and elsewhere, the judiciary have intervened to block anti-THR decisions. See box (top of page 126).

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[223] Callard, C. (2020, May 9). Physicians for a Smoke-Free Canada: Nova Scotia and Ontario move to curb high-nicotine vaping products. *Physicians for a Smoke-Free Canada.* http://smoke-free-canada.blogspot.com/2020/05/nova-scotia-and-ontario-move-to-curb.html

In Quebec, the Supreme Court overturned the state government provisions in its Tobacco Control Act 2015 which banned demonstrations of vaping devices in specialist shops and clinics and stopped the promotion of vaping aimed at those wanting to quit smoking.

This was an important development and came in the same month that saw the Swiss Federal Court overturn a ban on the import of snus, while more dangerous products are allowed. In 2018, a court in New Zealand overruled the Ministry of Health and allowed the importation of IQOS 'heets' arguing that if the New Zealand government's aim was to reduce the damage of smoking, how could it justify banning a product that did just that?

Latin America

To regulate, inspect and prosecute a commercial enterprise, you need an efficient bureaucratic structure to deploy inspectors and police at a national, regional and municipal level. In many LMIC, such structures are under-developed and under-funded and may be further undermined by corrupt practices. Officials will have many competing priorities and will often act only in response to public, press and political pressure against a perceived problem.

> There exists a huge informal economy in Latin America. When authorities cracked down on SNP, they simply succeeded in turning the market a darker shade of grey.

In many Latin American countries, the vaping industry inhabits a twilight zone between legality and illegality. In such circumstances where the laws are unclear and there is a sudden public scare about vaping, precipitate action can occur. During September-November of 2019 across the region, but especially in Mexico, Brazil and Argentina, there were raids on shops and goods seized. In February 2020, there was a presidential decree in Mexico banning vaping and HTP devices.

But within the legally grey market arena, for example, a seller might have to register with the authorities to sell devices in a shopping mall. Or sellers might have to register to sell general electrical goods and sell vaping devices on the side. Vaping sellers might ply their trade from a stand in the street or from a garage. Online selling is much harder to control.

There exists a huge informal economy, not just in Latin America but across the world, where goods of all kinds are traded on the edges or outside the law. When the authorities backed by campaigners in the region suddenly swing into action against THR and launch a crack-down, they simply succeed in turning the market a darker shade of grey.

Mexico

Vaping is not expressly mentioned in the General Law on Tobacco Control. The prohibition comes from an interpretation of a provision that bans non-tobacco products that resemble a tobacco product. While there are restrictions on marketing and advertising tobacco products, there are no outright smoking bans except in schools. The law provides for designated smoking areas in most locations and it appears unclear on a number of issues regarding where an individual can or cannot smoke. Mexico has nearly 7 million daily adult smokers, losing an estimated 49,000 people a year to a smoking-related disease, with overall over 1.2 million years of life lost due to premature death and disability because of smoking.[224] In 2015, public health spending attributed to smoking was $81 billion (Mexican pesos).

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[224] *Smoking in Mexico. Death, illness and tax situation.* (2017). IECS. https://www.iecs.org.ar/wp-content/uploads/Flyer_tabaquismo_MEXICO.pdf

Rolling tobacco. Image: Gresei on Adobe Stock

Despite this health burden, the Mexican government banned vaping (with effect from February 2020) on the basis of a section in the existing tobacco law which prohibits "marketing, selling, distributing, exhibiting, promoting or producing any object that is not a tobacco product, which contains any of the elements of the brand or any type of design or auditory signal that identifies it with tobacco products."

In November 2019, however, Mexico's Supreme Court upheld a challenge to the country's tobacco law, arguing it was too hard to sell vaping products. The court ruled the law is unconstitutional, saying it violates the rule of fair treatment. The court said that sales of vaping and similar products should be allowed "under the same conditions as products containing tobacco." For now, the ruling does not set a nationwide precedent. It applies only to the parties who filed the appeal.[225] But a review is currently pending.

Vaping device. Image: Ashley BYRD on Unsplash

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[225] *Mexico top court rules e-cigarette sales should be allowed.* (2019, November 14). AP NEWS. https://apnews.com/066c90 42871c4e60afea6dedf87c5b48

The irony is that the Mexican government has put forward a proposal to legalise cannabis in an attempt to reduce the huge death toll of drug-related violence – while apparently making it harder to reduce the human cost of smoking.

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Brazil

Since 2009, Brazil has banned the importation, distribution, sale and advertising of all vaping products. Despite the ban, use – including in open public spaces – is tolerated and there are more than a hundred online stores in operation. Individuals advertise and sell products through social networks like Instagram and in nightclubs, while vaping products are sold in tobacconists and in a few cases vape shops and convenience stores.

As in many countries, government agencies and medical organisations continue to mislead the public over the dangers of vaping, linking it to the VITERLI deaths in the US. Several parliamentarians have been individually proposing bills to ban or criminalise the use of vaping devices. Currently, there are multiple anti-THR bills being proposed at the federal, state and municipal levels, although the serious level of COVID-19 in the country is more of a public health priority and legislative progress is likely to be delayed.

Asia

India

After being on the slow burner for almost five years, the vaping debate in India heated up in September 2019 with the central government issuing an executive order to ban the sale and advertisement of vaping products and then enacting it into law after a contested, though largely uninformed, debate in Parliament. The ban covers the production, manufacture, import, export, transport, sale, distribution and storage, as well as advertisements, covering nicotine and non-nicotine vaping and HTP.

India has the second highest number of smokers globally, is a world leader in tobacco production, and has banned vaping products.

The usual soundbites about protecting young people were puzzling as it seems there are no published data concerning vaping among young Indians.[226] Instead, the government has taken its cue from the US and chosen to ignore any evidence contradicting the anti-vaping narrative. First time offenders face a 100,000 rupee fine ($1,000) and up to a year in jail. Simply possessing a vaping device is a 50,000 rupee fine ($660) and/or up to six months imprisonment. Sixteen Indian states had already passed anti-vaping laws.

India is a world leader in tobacco production; the government has a 28 per cent stake in the India Tobacco Company and tobacco farmers are an important voting bloc for political parties, as nearly 46 million people depend on the tobacco sector in India for their livelihood. India also exports around $1bn-worth of tobacco annually.[227]

Notwithstanding a population of 100 million cigarette smokers and an annual death toll of over 800,000, the government appears to be paying more heed to the threat posed to its industry from the likes of Philip Morris and JUUL who had both planned to launch products in the country.[228]

[226] Sharan, R. N. et al. (2020). Patterns of tobacco and e-cigarette use status in India: a cross-sectional survey of 3000 vapers in eight Indian cities. *Harm Reduction Journal*, 17(1), 21. https://doi.org/10.1186/s12954-020-00362-7

[227] Agence France-Presse. (2019, September 18). India bans e-cigarettes as global vaping backlash grows. *The Guardian*. https://www.theguardian.com/society/2019/sep/18/india-bans-e-cigarettes-as-global-vaping-backlash-grows

[228] Withnall, A. (2019, September 18). *India bans vaping after government passes emergency order.* The Independent. https://www.independent.co.uk/news/world/asia/india-bans-vaping-law-e-cigarettes-modi-disease-deaths-a9110201.html
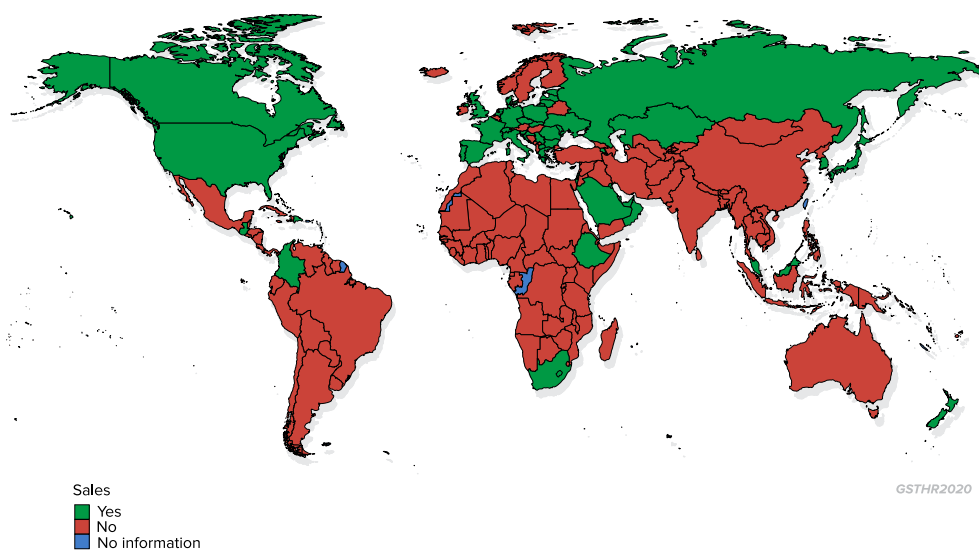
Japan

Image: Parker ULRY on Unsplash

In line with many high-income countries, Japan has seen significant declines in daily adult smoking rates, although it is behind in public smoking bans, preferring instead to have designated smoking areas. Japan toughened up laws in major cities like Tokyo ahead of the 2020 Olympic Games (now postponed until 2021), although protecting bystanders from second-hand smoke has been more driven by etiquette than legislation. Japanese smokers often carry ashtrays with them in order not to inconvenience others and to reduce litter.

Countries where heated tobacco products are marketed

Sales
- Yes
- No
- No information

GSTHR2020

GSTHR 2020

Given this culture of manners regarding smoking, it might have been expected that the authorities would have taken a reasonably liberal approach to SNP. But as nicotine is

In Japan, HTP devices have seen a dramatic rise in popularity with a consequential steep fall in cigarette sales.

listed as a poison, it means that vaping e-liquid is not allowed unless approved as a medicinal product, although devices and non-nicotine liquids are on sale. By contrast, rather than being the responsibility of the health ministry, HTP are controlled by the Ministry of Finance and are widely available. HTP devices have seen a dramatic rise in popularity among young smokers – with a consequential steep fall in cigarette sales – both because of the technological novelty and because HTP play to the culture of manners.

South Korea

South Korea is a tragic example of a country which has gone backwards in relation to THR. The main domestic tobacco company KT&G was a government monopoly until privatisation, since when it has pushed on with an ambitious growth plan. But with the arrival of SNP and in particular HTP, cigarette sales in South Korea went into reverse. Since smoking was banned indoors at places like restaurants and cafés in 2015, South Korea has become less tolerant of smokers. Meanwhile vaping products have been gaining popularity in the country's $16 billion tobacco market since 2017. By June 2019, vaping products accounted for 13 per cent of South Korea's nicotine market by sales, while for HTP, the country is currently the world's second largest market after Japan, worth $1.7 billion.[229]

Korea is a tragic example of a country which has gone backwards in relation to THR.

Unfortunately, the government has been influenced by the WHO and internal anti-THR elements – issuing warnings about SNP amid proposals to impose bans. The consequence of smokers being warned about the 'dangers' of vaping is that the rate of decline in cigarette sales has slowed. This can only benefit traditional cigarette companies and a government more concerned about falling tax revenue or damage to a domestic tobacco industry or both. Of course, this is a consequence of a more prohibitionist approach to SNP not limited to South Korea.

Philippines

Vaping products are regulated by the Department of Health (DOH) and the Food and Drug Administration (FDA) under *"Rules and Regulations on Electronic Nicotine Delivery System (ENDS) or Electronic Cigarettes"* issued in March 2014.[230]

Backed by influential NGOs like Health Justice and the Bloomberg-supported Southeast Asia Tobacco Control Alliance (SEATCA), health officials have consistently warned the public against "the adverse health effects and safety concerns associated with the use of e-cigarettes." According to the DOH, e-cigarettes contain "harmful chemicals...such as nicotine, ultra-fine particles, carcinogens, heavy metals, and volatile organic compounds." The agency cited "peer-reviewed studies", which showed that "e-cig juices contain high levels of addictive nicotine, which can result in acute or even fatal poisoning through ingestion and other means." The DOH claimed that there are "documented cases of nicotine toxicity in children of epidemic proportion" in "other countries with increasing prevalence of e-cigarette use" and that vapour contains harmful substances that can affect bystanders.

On 1st October 2019, a local court issued an injunction ordering the DOH and FDA not to implement an order that would have imposed restrictive regulations on vaping products. Set to take effect at the end of October, the order classified e-liquid refills

229 Cha, S. (2019, October 25). South Korea warns of 'serious risk' from vaping, considers sales ban. Reuters. https://www.reuters.com/article/us-health-vaping-southkorea-idUSKBN1X205E
230 References and documents for this section provided by local key informants.

as hazardous substances and the electronic delivery system as a health product. The order also sought to limit nicotine content of vaping products to 2 per cent and the amount of e-liquid in a container to 10 ml. There would be a ban on any form of advertising for vaping products and a ban on flavours for vaping products together with a ban on products falling within Category 1 and 2 of the Global Harmonized System ("GHS") labelling system;[231] and the requirement of a License to Operate (LTO) and marketing authorisations for retailers and manufacturers before they can deal in vaping products. The case was no longer pursued after President Duterte threatened court judges not to interfere with his 'vape ban'.[232]

In November 2019, President Duterte issued a verbal order banning the use of vaping devices in public places and directing the police to apprehend individuals caught vaping in public places. The order was prompted by the outbreak of VITERLI cases in the US and an alleged case in Cebu City. Although possessing a device was not a crime, the Philippine National Police confiscated at least 250 vaping devices across the Central Visayas, with 100 of them in Cebu City. According to news reports, some police officers even knocked on doors of vapers to confiscate their devices. An import ban was also imposed.

President Duterte threatened court judges not to interfere with his 'vape ban'.

Source: Wikimedia Commons
President Rodrigo Duterte of the Philippines

On December 18, 2019, Congress ratified the amended Sin Tax Law, increasing excise taxes on e-cigarettes effective from 1st January 2020. The tax rates for freebase e-liquids have been set at 45 per cent in 2020 rising to 60 per cent in 2023. For nicotine salts, tax rates rise from 37 per cent in 2020 to 52 per cent in 2023. Only plain tobacco or plain menthol flavours are allowed for sale. The legal age to buy vapour products in the Philippines is 21 years old.

As the case against the order collapsed, as of February 2020, all e-liquid solutions and vaping devices have to be registered with the FDA. Firms must also secure a license from the FDA before they can be operational. The sale, manufacture, marketing, distribution and importation of unregistered electronic nicotine devices and other novel tobacco products are banned, citing serious health threats to those who are exposed to the "smoke" (vapour).

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[231] The Globally Harmonized System of Classification and Labelling of Chemicals or GHS is managed by the UN concerning the labelling schemes for hazardous materials as well as their classification.

[232] Corrales, N. (2019, November 20). *Duterte warns judiciary not to mess with vaping, e-cigarettes ban*. INQUIRER.Net. https://newsinfo.inquirer.net/1192504/duterte-warns-judiciary-not-to-stop-his-ban-on-vaping

The use of unregistered vaping devices in public and enclosed spaces is prohibited. A new order aligned public vaping bans with existing smoking bans covering smoking of cigarettes in enclosed areas such as schools, elevators and stairwells, fire hazard locations and medical facilities.

In April 2020, the DOH appealed to smokers and vapers to stop immediately since they were perceived to be at a higher risk of contracting COVID-19. SEATCA also advised the public that the ongoing pandemic would be the best time to quit smoking and/or vaping.

Oceania

New Zealand

Until recently, vaping products were banned unless medically approved. Increasingly though, the government has taken more of a harm reduction approach. In 2017, the Ministry of Health released a statement on vaping products which concluded that:

> *"Expert opinion is that vaping products are significantly less harmful than smoking tobacco but not completely harmless…Smokers switching to vaping products are highly likely to reduce their health risks and for those around them."*[233]

The government stated publicly that vaping products could be valuable tools in helping the country go smoke free by 2025.

The government has introduced new legislation focused on SNP, although it has not quite delivered on the promise indicated in previous THR-supporting statements. Nonetheless, proposals have been generally welcomed by consumer activists especially, unlike the EU TPD, as there is no limit on nicotine content, or liquid quantity per bottle. At the time of writing, the Bill is going through the parliamentary process.[234]

The main points of the Smoke-free Environment and Regulated Products (Vaping) Amendment Bill amending the Smoke-free Environments Act 1990 are:

» Sale of all products aged restricted at 18.
» Advertising and sponsorship prohibited.
» Vaping and heated tobacco use prohibited in smoke-free areas such as indoor workspaces.
» Online sales allowed.
» Product notification system to be introduced.
» Only tobacco, mint and menthol flavours to be sold at generic retailers (supermarkets, convenience stores etc). Specialist vape retailers can sell other flavours.
» Generic retailers are not able to display or advise on a product.
» Specialist vape retailers can display, advise, make recommendations, and demonstrate products where vaping is also allowed and sellers can provide giveaways, discount or loyalty points. All this is forbidden to generic sellers.

Australia

Despite some green shoots of support from medical associations, Australian federal and state governments remain implacably opposed to changing the laws in order to promote tobacco harm reduction. The country was a leading light in anti-smoking

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[233] *Vaping and smokeless tobacco. Position Statement on vaping.* (2017). Ministry of Health NZ. https://www.health.govt.nz/our-work/preventative-health-wellness/tobacco-control/vaping-and-smokeless-tobacco
[234] Although at the time of writing, the government is actively considering a ban on oral SNP such as snus.

campaigns of the past, was the first country to introduce plain packaging and is home to some of the more virulent anti-THR activists.

At a federal level, devices are legal to buy, but not liquids containing nicotine, which is regulated as a poison and only available on prescription, the exception being NRT products. The government announced in June a ban on all imported vaping products containing nicotine with a potential fine of AUS$220,000 for personal use of imported products (nearly three times the average national salary) although at the time of writing, the proposal is under review.

The regulations across the states follow the same federal tack wherein pretty much everything to do with the sale, advertising and use of SNP is banned, although there are some anomalies. For example, in Western Australia vaping is allowed in smoke-free areas, but anybody arrested for possession of nicotine without a prescription faces the highest fine of any state set at AUS$45,000 ($33,000). In the Northern Territories, you can go to prison for a year for unauthorised possession, but there are no restrictions on advertising, sales to minors of non-nicotine liquid or places where you can vape.

There has been a significant amount of media discussion on the dangers of a growing market in illegal cigarettes as a consequence of rising taxation with little sign that taxation is actually reducing smoking among the poorest in society, rather than pushing them towards illegal and cheaper alternatives. However, none of this is having any impact on policy debates as to how liberalising the laws on THR might both improve health and damage the illicit cigarette market.

While domestic rules might be strict, policing internet sales is a very different matter: a significant number of consumers are buying unregulated products from nearby markets in Asia. This lack of regulation puts the estimated quarter of a million Australian SNP consumers at risk.

Africa

SNP have yet to make significant inroads into Africa and few countries have specific laws relating to sale, use etc. Vaping devices are sold in Nigeria for example, though priced at a level that puts them out of many people's reach.[235] Vaping is usually allowed in special designated smoking areas. Uganda banned SNP in 2015, while Kenya is the only country in Africa to tax e-cigarettes.[236]

South Africa has the most developed SNP market worth an estimated R1 billion ($58m) and supporting around 4,000 full time jobs.[237] In 2018, the government introduced The Control of Tobacco and Electronic Delivery Systems Bill with some of the toughest anti-smoking laws in Africa and making no distinction between cigarettes and SNP, including an attempt to legislate against tobacco use at home. This has yet to be enacted. Meanwhile, at the end of March 2020, in response to COVID-19, the government banned the sales of alcohol and all tobacco products. In June, while restrictions on alcohol sales were lifted, the tobacco ban remained in place, but with little effect as a study from the University of Cape Town revealed.[238]

[235] Olatunji, U. (2020, March 30). Nigeria Is Crying Out for Vapes That Smokers Can Afford. *Filter*. https://filtermag.org/nigeria-vapes-afford/

[236] *E-Cigarettes: Use and Taxation (English)* (WBG Global Tobacco Control Program.). (2019). World Bank Group. http://documents.worldbank.org/curated/en/356561555100066200/E-Cigarettes-Use-and-Taxation

[237] Daniel, L. (2018, August 15). New smoking laws set to extinguish vaping in South Africa. *The South African*. https://www.thesouthafrican.com/news/new-smoking-laws-vaping-in-south-africa/

[238] Norcia, A. (2020, May 28). How South Africa's Coronavirus Tobacco Prohibition Backfired. *Filter*. https://filtermag.org/south-africa-coronavirus-cigarettes-ban/

Product safety: a matter of global concern

A key requirement for SNP consumers, wherever they live in the world, is to be assured of the quality of the products they are using.

We live in a world full of counterfeit goods: fashion and fashion accessories, technology, watches, medicines and so on. SNP are no different in this respect. Almost as soon as it was launched, fake IQOS devices were in circulation.

Given that currently there are around 68 million vapers worldwide, the incidence of devices catching fire or exploding is rare, although will inevitably be reported in the media. This can happen for a number of reasons, primarily consumer error in constructing their own devices, but also poorly made counterfeit devices and poorly made or cheap batteries where the contacts are exposed and come into contact with a metal object like keys in a consumer's pocket.

There are some potential quality issues around large bottles of non-nicotine e-liquids known as short-fills, or shake and vape - so named because they are not filled to the top, allowing users to add their own bottle of nicotine. Short-fills developed as a get around for the EU Tobacco Products Directive (TPD) rules dictating that nicotine containing e-liquids need to be tested and notified and can only be sold in 10ml bottles. As short-fills fall outside the TPD they are much cheaper to bring to market than nicotine containing e-liquids and so are available in many more flavours. UK vaping trade bodies have been calling for all vapable liquids, including short-fills, concentrates and any vapable cannabis product, to be notified to the UK MHRA.

Image: CDC on Unsplash

Safety standards

A number of international, regional and national bodies have developed or are developing standards for SNP.

The International Organisation for Standardisation (ISO) is an independent NGO with a membership comprising standards organisations of 162 member countries. It is the world's largest developer of voluntary international standards and facilitates world trade by providing common standards between nations. Over 20,000 standards have been set, covering everything from manufactured products and technology, to food safety, agriculture and healthcare.

The ISO tobacco committee has established a vaping products sub-committee with two working groups, looking at safety and quality requirements for vaping devices and e-liquids, test methods for devices and e-liquids, determination of substances in e-liquids, testing conditions, equipment, reference products, emissions, vaping machines and user information and services provided by retailing.[239] There are now six standards specific to vaping liquids and devices, covering the composition of e-liquids and emissions from those devices – two are published and four are under development.[240]

At the regional level there is the European Committee for Standardisation or CEN, which has four working groups covering devices, e-liquids and emissions. The CEN technical report *Electronic cigarettes and e-liquids – constituents to be measured in the aerosol of vaping products* was published in 2018 and provided "a list of constituents of interest":

» Prefilled products such as disposable devices and refill cartridges.
» E-liquids sold in refill containers.
» The following categories of hardware: coils or other heater elements of the vaping product, atomisers, rebuildable atomisers and all open tank or dripper products with inbuilt atomisers, including clearomisers.

The CEN states:

> "These standards will provide a common framework for all electronic cigarettes and e-liquid products sold in all EU markets. This work also aims to increase the safety of all the European users, by setting consistent safety and quality standards of the products and improving consumer information across all EU Member States. These documents, recognized and applicable in all CEN members' countries, will give advice and help manufacturers, importers, exporters and distributors to adhere to standardised safety and quality requirements".

To what extent the standard will now apply to the UK remains to be seen.[241]

In the UK, the British Standards Institute (BSI) produced PAS 54115 in 2015, a manufacture, importation, testing and labelling guide covering vaping products, including devices, e-liquids and e-shisha. Subjects covered include: the purity of e-liquid ingredients; potential contaminants from device materials and potential emissions from devices; an outline for the toxicological and chemical analysis of emissions; and, the safety of batteries and chargers. The BSI have now published PAS 8850:2020, *Non-combusted tobacco products – Heated tobacco products and electrical tobacco heating devices – Specification*.[242]

The French Association Française de Normalisation (AFNOR) has published similar guidance standards.

There is a voluntary product standard for Swedish snus called the Gothiatek standard, introduced by the snus industry in 2001.[243] In 2007, the Gothiatek standard was accepted as a standard for all smokeless tobacco products

[239] Tranchard, S. (2016, April 21). *Vape and vapour products make their debut in international standardization*. ISO. https://www.iso.org/cms/render/live/en/sites/isoorg/contents/news/2016/04/Ref2074.html
[240] *ISO – ISO/TC 126/SC 3 – Vape and vapour products*. (n.d.). Retrieved 1 July 2020, from https://www.iso.org/committee/5980731/x/catalogue/
[241] *CEN/TR 17236:2018*. (2018, September 26). European Committee for Standardization. https://standards.cen.eu/dyn/www/f?p=204:110:0::::FSP_LANG_ID,FSP_PROJECT:25,65461&cs=1369EF3BCBACA65582FFB337FE84BA1B3
[242] *PAS 8850:2020 heated tobacco products specification*. (2020, July). British Standards Institution. https://shop.bsigroup.com/ProductDetail?pid=000000000030396623
[243] Rutqvist, L. E. et al. (2011). Swedish snus and the GothiaTek® standard. *Harm Reduction Journal*, 8, 11. https://doi.org/10.1186/1477-7517-8-11

(STP) by the European Smokeless Tobacco Council (ESTOC), an organisation representing all the major manufacturers of snus.

The Gothiatek standard sets maximum permissible levels for several unwanted substances. The mandated maximum levels have been lowered on several occasions since the introduction of the standard. In 2010, the WHO Study Group on Tobacco Product Regulation proposed maximum levels for some nitrosamines (NNN, NNK) and one PAH (BaP, benzo(a)pyrene) in STPs. These levels are, however, higher than the maximum levels currently mandated by Gothiatek as well as below the maximum levels for snus set by the Swedish Food Authority which came into force on 11th April 2016.[244]

The direction of travel in many countries is to enact more stringent controls on SNP, either aligning regulations with controls on tobacco, enacting flavour bans or worse.

This type of policy is driven by a view of SNP as a threat to public health rather than an opportunity to complement existing efforts at reducing the effects of the smoking epidemic. Another underlying driver of the anti-THR narrative may be that the whole enterprise has been driven from the bottom up by consumers and brought to a wider market by commercial interests, taking it out of the hands of public health agencies entirely.

Whatever the context or motive, anti-THR policies are in breach of a clutch of international treaties which declare the universal right to health with nobody left behind.

But whatever the context or motive, anti-THR policies are in breach of a clutch of international treaties which declare the universal right to health with nobody left behind.

The worst impacts of SNP prohibition will be experienced by smokers and those already-marginalised groups who smoke the most and consequently suffer most from smoking-related disease and death: indigenous communities, LGBTQ+ communities, those in prison, the homeless, those in extreme poverty and those suffering mental health, drug and alcohol problems.

244 Swedish Match – Snus and the Swedish Food Act. (2016). https://www.swedishmatch.com/Snus-and-health/snus-and-the-swedish-food-act/

Chapter 7
The right to health
and the people left behind

The notion of non-smokers' right to health – especially bystanders and children – underpinned much of tobacco control developments through the 1980s and 1990s. Those involved in the campaigns, especially in the US, saw themselves as warriors battling the economic and political interests of tobacco companies. Backed by the evidence of the damage caused by smoking and the increasing efforts to ban public smoking, campaigners seized the moral high ground as smokers became the new social pariahs.

But the tables have turned; those whose rights need protecting now are those who want to switch away from smoking and towards the use of safer products. Sabotaging these rights are many of the same individuals and organisations (along with new actors) who heavily influenced national and international tobacco control policies leading up to the FCTC. And like the tobacco companies, the anti-THR lobby has vested financial and political interests in maintaining the tobacco control status quo. There is funding from anti-THR bodies like Bloomberg Philanthropies (BP) who have power and influence around the policy table, coupled with the economic interests of Big Pharma and some domestic tobacco industries both lobbying to legislate SNP out of existence.

The fundamental purpose of tobacco control – to reduce the harm from smoking – seems lost in a miasma of competing interests inimical to the human rights aspects of public health.

Image: Hosein EMRANI on Unsplash

The fundamental purpose of tobacco control – to reduce the harm from smoking – now seems lost in a miasma of competing interests inimical to the human rights aspects of public health. Yet there is a clutch of international treaties cementing universal health for all as a fundamental human right. The FCTC in its own words declares its commitment to these fundamental rights in:

Those whose rights need protecting are those who want to switch away from smoking towards the use of safer products.

> "Recalling *Article 12 of the International Covenant on Economic, Social and Cultural Rights, adopted by the United Nations General Assembly on 16 December 1966, which states that it is the right of everyone to the enjoyment of the highest attainable standard of physical and mental health,*

"Recalling also *the preamble to the Constitution of the World Health Organization,which states that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition,*

"Recalling *that the Convention on the Elimination of All Forms of Discrimination against Women, adopted by the United Nations General Assembly on 18 December 1979, provides that States Parties to that Convention shall take appropriate measures to eliminate discrimination against women in the field of health care.*

"Recalling further *that the Convention on the Rights of the Child, adopted by the United Nations General Assembly on 20 November 1989, provides that States Parties to that Convention recognize the right of the child to the enjoyment of the highest attainable standard of health.*"

Although undefined, Article 1 of the FCTC specifically states that tobacco control means "a range of supply, demand and **harm reduction strategies** that aim to improve the health of a population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke" [emphasis added]. There was also a commitment to "promote measures of tobacco control based on current and relevant scientific, technical and economic considerations".

International trade law and policy expert Marina Foltea writes:

"The fact that health is recognised as a right under international law demonstrates that public health is of the utmost importance for most nations. It amounts to a universal recognition that the protection of human health is a responsibility that must be undertaken by all States."

She goes on to say that "States are obliged to abstain from illegitimate interference with the rights of individuals to protect their own health", rather they have "to take deliberate and active steps towards the full realization of human rights".[245]

By making it difficult, if not impossible, for current smokers to access SNP, governments are illegitimately interfering with an individual's right to health. The WHO is colluding in this by not clearly defining what it means by 'harm reduction' in the FCTC, and by narrowly defining human rights as the right to be protected from the tobacco industry.

> By making it difficult if not impossible for current smokers to access SNP, governments are illegitimately interfering with an individual's right to health.

This absence of a properly-defined and implemented harm reduction 'pillar' in the FCTC to sit alongside the three established pillars to prevent initiation, promote cessation and protect from environmental impact was criticised by Meier and Shelley as far back as 2006.

In the light of the fact that many nations were failing to deliver on what the authors call the first three pillars of the FCTC, they wrote in a period before the global take-up of SNP that:

"unlike cessation efforts, nations need not do anything to introduce a harm reduction strategy; private corporations already are developing and marketing... products without government encouragement...Countries can work together within WHO to address issues of tobacco harm reduction, aiding each other in disseminating these results of basic science and translating these results into novel behavioural treatments, pharmacological regimes and tobacco products".[246]

[245] Foltea, M. (2019). Regulatory Restriction Of E-Vapor Products Under International Human Rights Law. *R Street*, 189. https://www.rstreet.org/2019/11/18/regulatory-restriction-of-e-vapor-products-under-international-human-rights-law/
[246] Meier, B. M., & Shelley, D. (2006). The Fourth Pillar of the Framework Convention on Tobacco Control: Harm Reduction and the International Human Right to Health. *Public Health Reports*, 121(5), 494–500. P. 494-500.

THR offers a global opportunity for one of the most dramatic public health innovations ever to tackle non-communicable disease and at minimal cost to governments. In a time of COVID-19 when global health and public finance systems are stretched to breaking point and may not recover for some time, the imperative to drive forward with THR has never been more urgent.

Image: Akhila KATURI on Unsplash

In this report, we also 'recall' the 1986 Ottawa Charter on Health Promotion which categorically stated:

> *"Health promotion focuses on achieving equity in health. Health promotion action aims at reducing differences in current health status and ensuring equal opportunities and resources...People cannot achieve their fullest health potential unless they are able to take control of those things which determine their health."*

Regarding the death and disease toll from smoking (among many other health issues), there seems little evidence of 'equity in health' for a very broad spectrum of the global population including specific groups who are demonstrably 'left behind'.

THR and the people left behind

All smokers can benefit from switching away from using combustible tobacco products. But some groups are especially vulnerable to the consequential risks of smoking because smoking levels in these groups are higher than the wider population. These comprise groups we call 'the left behind'.

At a global level, the 'left behind' include those living in social and economic poverty and deprivation. Most of the world's smokers live in the poorest countries where there is little or no access to SNP as the products are not available at prices that the poorest can afford. Even in higher income countries, compared with the price of cigarettes, SNP are generally only available to those with sufficient disposable incomes, located largely within middle class communities.

'The left behind' are those especially vulnerable to the risks of smoking and least able to access SNP.

One area of concern which appears completely ignored in this debate is the economic impact of smoking deaths and disease on families in the poorest countries. These countries house the world's largest populations of smokers, who are invariably men. It is men who are typically the main breadwinners while women remain at home looking after the family and household. Should the breadwinner be lost to smoking-related disease, the situation for women, already in a precarious economic situation can only worsen.

More specifically, the left behind can be identified as those living in marginalised and stigmatised groups like the LGBTQ+ and minority ethnic communities; those suffering mental health problems, homelessness, drug and alcohol problems; and those who are incarcerated. And these are not discrete issues; for millions of individuals, life is a daily struggle against intersecting discrimination and stigma. Individuals in these communities and social groupings suffer disproportionate levels of physical and mental ill-health compared to the general population looking for ways to cope with stress and anxiety and as a vector for socialising and communication. Smoking helps fulfil these psychological and social needs.

As Dr Marewa Glover and colleagues recently commented:

> "The WHO target [of reducing global tobacco use] is unintentionally, but effectively, misdirecting the sector from focusing on how to reduce the incidence of smoking-related diseases, which is the real goal. The dictum to focus on reducing global tobacco use encourages a utilitarian focus on achieving behaviour change among as many people as possible for the least cost, regardless of unexpected negative consequences for the few. The least costly interventions are laws, regulations, taxes and mass media campaigns – blunt instruments applied state-wide or nationally. In this strategy, effectiveness is measured at a population level, using averages that erase outliers, such as disproportionately high smoking prevalence among subgroups. The policies are assessed for their potential to benefit the many, that is the most populous group, and this is usually the politically dominant group. ...Policies and laws designed to benefit the politically dominant group, inevitably leave aside the effects on minorities".[247]

"Without radical changes in our approach to tobacco control, unacceptable disparities in smoking-related disease and death may persist for decades."

In an editorial in *The American Journal of Public Health*, Daniel Giovenco commented that:

> "harm reduction approaches...have the potential to accelerate the smoking 'endgame' and reduce inequalities more rapidly and effectively than traditional control initiatives...Without radical changes in our approach to tobacco control, unacceptable disparities in smoking-related disease and death may persist for decades".[248]

Separating out the diversity of left behind and vulnerable groups is somewhat artificial because they share many common problems. But for the purposes of illustration in this report, we draw attention to four groups; indigenous communities; LGBTQ+ communities; prisoners and those suffering mental illness, a substance use problem or are homeless.

Indigenous populations[249]

Indigenous or first nation people live in over 90 countries, numbering around 370 million, making up 5 per cent of the global population. Largely due to the multiple negative social, racial, political and economic impacts of colonisation over centuries, they account for about 15 per cent of the global poor.

247 Glover, Marewa et al. (2020). Tobacco smoking in three "left behind" subgroups: indigenous, the rainbow community and people with mental health conditions. *Drugs and Alcohol Today, ahead-of-print*(ahead-of-print). https://doi.org/10.1108/DAT-02-2020-0004

248 Giovenco, D. P. (2019). Different Smokes for Different Folks? E-Cigarettes and Tobacco Disparities. *American Journal of Public Health*, 109(9), 1162–1163. https://doi.org/10.2105/AJPH.2019.305250, p. 1162-63. This author was also the lead author of a study which looked at sales of combustible tobacco products and SNP in socio-demographically diverse part of New York City. The authors concluded, "The marketing of inexpensive, combusted tobacco products disproportionately saturates low-income, minority communities, while potentially lower risk, non-combusted products are more accessible in largely White and higher income neighbourhoods. This pattern may exacerbate tobacco-related inequities. Public health policies should prioritize reducing the appeal and affordability of the most harmful tobacco products to help reduce health disparities". Giovenco, D. P. et al. (2019). Neighborhood Differences in Alternative Tobacco Product Availability and Advertising in New York City: Implications for Health Disparities. Nicotine & Tobacco Research, 21(7), 896–902. https://doi.org/10.1093/ntr/nty244

249 Information on indigenous populations relies on the work of Dr Glover, an expert in the health inequalities suffered by indigenous groups especially as they apply to smoking and the options for SNP to reduce mortality and morbidity.

One consequence of being left behind outside of the political mainstream is the paucity of data about many aspects of indigenous life, including smoking. But such data as exists indicates high prevalence of smoking among indigenous peoples. So, 83 per cent of Yolŋu men in remote Arnhem Land communities in Australia smoke. In Russia, there are 47 different recognised groups with much variation in smoking rates, the highest possibly among Nenets men at 74 per cent, living in the northern Arctic region.

Many of these populations living in North America, Oceania, and Pacific regions have long-standing tobacco-using traditions with social and cultural landscapes very different from those observed in non-indigenous communities. For example, in New Zealand, smoking rates among Māori women are much higher than non-Māori women.

In 2019, Dr Glover made a submission to the Danish government concerning the Kalaalit Nunatt people of Danish-administered Greenland pointing to all the diverse ways in which colonisation has impacted on the health and wellbeing of the people (compared to other Nordic countries) and how one-size-fits-all Nordic tobacco control policies are potentially damaging to this population. Smoking rates are very high; similar to smoking among Māori people, more women smoke (57 per cent) than men (43 per cent). Lung cancer is the most prevalent form of cancer in the country while 35 per cent of pregnant women smoke.

In light of the high rates of smoking-related diseases suffered by the people, Dr Glover outlined all the key arguments in favour of THR, referencing the dramatic fall in cigarette sales in Norway and Sweden where snus is allowed and the more liberal approach to vaping control in Iceland.

Dr Glover cites much criticism of tobacco prevention measures which fail to take account of the varieties of traditions which exist among indigenous populations despite one of the principles of the FCTC being "the need to take measures to promote the participation of indigenous individuals and communities in the development, implementation and evaluation of tobacco control programmes that are socially and culturally appropriate to their needs and perspectives" (Article 4.2c). In reality, there has been little or no progress globally. Not surprisingly, attempts to superimpose dominant template mainstream interventions have little or no impact.

That said, there are some encouraging green shoots around THR. The Sami people from northern Scandinavia and Finland have been making the transition from smoking to snus. In New Zealand, one of the few countries to adopt a more pragmatic and proportionate legal response to THR, Māoris have opened vape shops. As part of the process of encouraging Māori smokers to switch, a small programme called Vape2Save has been running for years and is currently being evaluated.[250]

Image: Olivier Le MOAL on Adobe Stock

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[250] *Vape2Save | Hāpai | Hāpai te Hauora*. (2017, February 15). https://hapai.co.nz/content/vape2save-h%C4%81pai

LGBTQ+ communities

In western countries, smoking rates among LGBTQ+ communities have often been reported at twice that of the heterosexual population. Common to all groups under this heading are the daily stresses and strains of being subjected to discrimination and even violence due to gender and sexual identity differences. Not surprising then, that these groups suffer high rates of anxiety, depression and suicide accompanied by high levels of smoking, drinking and drug use. There were some additional factors favouring smoking; in gay men for example, fear of weight gain has been cited.[251]

Image: Tristan BILLET on Unsplash

The literature is very sparse on levels of SNP among LGBTQ+ communities[252,253] although one US study suggested that levels of ever-vaping tended to match that of younger people in the general population.[254] Equally sparse are studies relating to smoking cessation interventions. Where community members have been surveyed, the general view seems to be that, given the diversities within the LGBTQ+ community, quite specific culturally-appropriate interventions are required.[255,256] Where some cessation interventions have been studied, the primary tools have been counselling, NRT and medications.[257] It does not appear that any studies have been published comparing cessation intervention which include SNP.

[251] Schwappach, D. L. B. (2009). Queer quit: gay smokers' perspectives on a culturally specific smoking cessation service. *Health Expectations: An International Journal of Public Participation in Health Care and Health Policy*, 12(4), 383–395. https://doi.org/10.1111/j.1369-7625.2009.00550.x

[252] For example, Buchting, F. O. et al. (2017). Transgender Use of Cigarettes, Cigars, and E-Cigarettes in a National Study. *American Journal of Preventive Medicine*, 53(1), e1–e7. https://doi.org/10.1016/j.amepre.2016.11.022

[253] Huang, J. et al. (2016). Electronic Cigarettes Among Priority Populations: Role of Smoking Cessation and Tobacco Control Policies. *American Journal of Preventive Medicine*, 50(2), 199–209. https://doi.org/10.1016/j.amepre.2015.06.032

[254] Mirbolouk, M. et al. (2018). Prevalence and Distribution of E-Cigarette Use Among U.S. Adults: Behavioral Risk Factor Surveillance System, 2016. *Annals of Internal Medicine*, 169(7), 429–438. https://doi.org/10.7326/M17-3440

[255] Berger, I., & Mooney-Somers, J. (2015). *Smoking Cessation Programs for LGBTI People: A Systematic Review of Content and Effect*. VELiM, University of Sydney. https://core.ac.uk/display/41241428

[256] Bruce Baskerville, N. et al. (2018). A qualitative study of tobacco interventions for LGBTQ+ youth and young adults: overarching themes and key learnings. *BMC Public Health*, 18. https://doi.org/10.1186/s12889-018-5050-4

Prisoners

Image: Tomasz ZAJDA on Unsplash

Smoking is an entrenched part of prison culture, not least because tobacco itself is a currency in many prisons. Coming largely from economically and socially disadvantaged communities, most of those subject to jail time are already smokers. Studies from different countries put smoking levels at up to 80 per cent.[258]

Smoking helps prisoners deal with the manifest stresses of incarceration: boredom, isolation from family as well as the constant risk of violence and intimidation.[259]

Prison is a difficult environment in which to conduct smoking cessation sessions, but surveys have shown that many prisoners want to feel they have achieved something inside and stopping smoking can be quite high on the list.

Since 2018, UK prisons have become smoke-free, but at the same time the potential benefit of allowing vaping was recognised. Ahead of the ban in Scotland, free tamper-resistant vaping kits were handed out where vaping itself had previously been banned. Pilot projects involving SNP were rolled out in England and Wales from 2015. As a recent ASH UK briefing reports:

> *"Initially only disposable e-cigarettes were available but after trials, rechargeable devices were introduced. In addition, an advance purchase scheme was introduced for prisoners with insufficient funds to purchase e-cigarettes to reduce debt and other associated problems. The provision of e-cigarettes is considered by HM Prison Service to be a game-changer in helping facilitate a successful transition to prisons being smoke free. Prior to the project starting, around 50,000 prisoners were buying tobacco, as of July 2018, prison shops were selling over 65,000 vaping products weekly to over 30,000 prisoners and sales have continued to increase since then".*[260]

[257] Eliason, M. et al. (2012). The Last Drag: An Evaluation of an LGBT-Specific Smoking Intervention. *Journal of Homosexuality*, 59, 864–878. https://doi.org/10.1080/00918369.2012.694770

[258] Baybutt, M. et al. (2012). Tobacco use in prison settings: A need for policy implementation. In *Prison Health Guide*. World Health Organisation. http://www.uclan.ac.uk/5413/

[259] Richmond, R. et al. (2009). Tobacco in prisons: a focus group study. *Tobacco Control*, 18(3), 176–182. https://doi.org/10.1136/tc.2008.026393

[260] ASH Briefing: The implementation of smokefree prisons in England and Wales. (2018, November 27). *Action on Smoking and Health*. https://ash.org.uk/information-and-resources/briefings/ash-briefing-the-implementation-of-smokefree-prisons-in-england-and-wales/

Prison officials have said that allowing vaping has reduced the amount of cigarettes and tobacco being smuggled in following smoking bans and consequently reduced levels of violence.

In the US, there are vape companies with contracts to supply modified vaping devices throughout the prison system, a trend which started as early as 2014.[261] Prison officials have said that allowing vaping has reduced the amount of cigarettes and tobacco being smuggled in following smoking bans and consequently reduced levels of violence.

THR for people with mental health issues

In the UK, 40-80 per cent of people with a mental health condition smoke and they consume 42 per cent of all tobacco, smoking more heavily and frequently. While smoking prevalence among UK adults has dropped to around 15 per cent, smoking rates among those with mental health problems have remained stubbornly unchanged for around 20-30 years.[262]

In one meta-analysis across 20 countries, those with a diagnosis of schizophrenia had an average smoking prevalence of 62 per cent while a study of US veterans with PTSD had a smoking prevalence nearly double that of veterans without PTSD.[263]

It is hard for people with a diagnosis of mental illness to break the smoking habit – there is a fear of change and a low motivation to quit amid competing and more immediate priorities. Cigarettes perform useful functions in daily life; dealing with boredom; regulation of emotions; development of routines around smoking; and opportunities for socialisation by sharing cigarettes similar to office workers gathering around the coffee machine or water cooler. But these benefits come at a price.

Smoking is the primary cause of the 15-25 years mortality gap between users of mental health services and the general population.

Smoking is the primary cause of the 15-25 years mortality gap between users of mental health services and the general population. Bearing in mind that the highest levels of smoking correlate with the most deprived areas in the UK (and elsewhere), data on health inequalities similarly reveals that rates of chronic obstructive pulmonary disease (COPD) and asthma are significantly higher in those most deprived regions. Respiratory and cardiovascular death rates for those under 75 with a diagnosis of severe mental illness are 4.7 and 3.3 times higher per 100,000 people than the general population respectively.[264,265,266]

English health authorities have taken a progressive view on allowing vaping in mental health settings. Encouraged by the guidance on THR provided by Public Health England and the NHS, vaping is being studied and trialled in smoking cessation interventions with mental health service users. In a survey of NHS mental health trusts conducted in 2019 by ASH, 91 per cent allowed the use of vaping devices alongside other cessation interventions, mainly NRT.[267]

[261] Walters, E. (2014, July 19). Texas Sheriffs Mull Selling E-Cigarettes to Inmates. *The New York Times*. https://www.nytimes.com/2014/07/20/us/texas-sheriffs-mull-selling-e-cigarettes-to-inmates.html;
Cornwell, L. (2015, February 17). *SC among several states allowing e-cigarette sales in jails. Greenvilleonline.* https://www.greenvilleonline.com/story/news/local/south-carolina/2015/02/17/cigarette-jails-sales-bans-south-carolina/23564139/
[262] Ryan, F. (2019, September 30). *The psychology behind smoking cessation – Mindsets, culture and preventing relapse.* Smoking Cessation and Mental Health Summit, Royal Society of Medicine, London.
[263] *Smoking and Mental Health* (No. 12; Fact Sheet). (2019). Action on Smoking and Health. https://ash.org.uk/information-and-resources/fact-sheets/health/smoking-and-mental-health/, p.5
[264] Health Matters: Smoking and mental health – Public health matters. (2020, February 26). [Blog]. *Public Health Matters.* https://publichealthmatters.blog.gov.uk/2020/02/26/health-matters-smoking-and-mental-health/
[265] *Likelihood of smoking four times higher in England's most deprived areas than least deprived.* (2018, March 14). Office for National Statistics. https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/drugusealcoholandsmoking/articles/likelihoodofsmokingfourtimeshigherinenglandsmostdeprivedareasthanleastdeprived/2018-03-14
[266] *Health profile for England: 2018.* (2018, September 11). Public Health England. https://www.gov.uk/government/publications/health-profile-for-england-2018/chapter-2-trends-in-mortality#premature-mortality-among-people-with-serious-mental-illness-smi
[267] Progress towards smokefree mental health services. (2019, October 29). *Action on Smoking and Health.* https://ash.org.uk/information-and-resources/reports-submissions/reports/progress-towards-smokefree-mental-health-services/

One Italian pilot study involved 40 outpatients with a diagnosis of schizophrenia spectrum disorders (who were not motivated to quit smoking) and using high nicotine content JUUL. After 12 weeks 40 per cent were determined to stop smoking and 52 per cent were determined to cut down. Across the board there were improvements in blood pressure, heart rate and exhaled carbon monoxide. Encouragingly, no significant side effects and negative changes in symptoms of schizophrenia were experienced.[268]

South London and Maudsley NHS Foundation Trust (SLAM) in England provides both mental health and substance use services. Despite going totally smoke free from October 2014, the Trust has allowed vaping across the whole organisation, going a step further in February 2017 from allowing only disposal devices to widening the type of devices used subject to individual risk assessment. Patients can vape in single bedrooms and anywhere outdoors in the hospital grounds.

THR for people with substance use issues

There is also a high level of smoking among those with substance use problems which can exacerbate drug-related health issues. Services around the world report in excess of 85-90 per cent of those attending for treatment also smoking tobacco.

In recent years, drug-related deaths in the UK have been rising, particularly among older, long-term users also suffering from smoking-related diseases such as COPD which generally ranks high in the list of co-morbidities for those addicted to opiates. In a cohort study of 845 users in residential substance use treatment in the USA, around a quarter died during the course of the study, with smoking-related causes outstripping those related to drugs and alcohol.[269]

Treatment staff are often reluctant to engage clients in discussions about smoking, not least because a high percentage of staff are also smoking but also because they feel that dealing with alcohol or drug problems is enough for the person to cope with. Clients can be left with the feeling that either the drug worker didn't think smoking was much of a problem or had no confidence in the client's motivation or ability to change. But often users are well aware of the risks of smoking and are often keen to quit, but like the general population of smokers do not find traditional cessation interventions that useful.

In a cohort study of 845 users in residential substance use treatment in the USA, around a quarter died, with smoking-related causes outstripping those related to drugs and alcohol.

SLAM in London have also been engaging with drug treatment clients using a range of vaping devices. Client feedback was encouraging; after the second session, 77 per cent reported that the devices were easy to refill and charge and nearly half rated the experience, ranging from "a little" to "much more satisfying than smoking". Reported feedback included:

"I'm so grateful that I've been given this opportunity…it's saved my life."

"This was the last thing to go. I've kicked everything else."[270]

[268] Pasquale, C. (2019, June 14). *Role of a new generation e-cigarette on smoking displacement in smokers with schizophrenia spectrum disorders (SSD)*: a single arm pilot study. Global Forum on Nicotine, Warsaw. https://gfn.net.co/downloads/2019/presentations/Pasquale_Caponnetto.pdf

[269] Hurt, R. D. et al. (1996). Mortality following inpatient addictions treatment. Role of tobacco use in a community-based cohort. *JAMA*, 275(14), 1097–1103. https://doi.org/10.1001/jama.275.14.1097

[270] Keller, M and Robson, D. (2020). *Tobacco harm reduction in Lambeth Addictions Consortium*. Smoking, drugs and alcohol conference, Birmingham.

THR for people experiencing homelessness

The health fall-out from smoking is no less a problem for homeless people for whom the cigarette provides the whole panoply of benefits including emotional calming, relief from boredom and socialising aspects.[271,272] However, the desire to quit smoking seems no less for homeless people than for other disadvantaged groups, but of course their homeless status makes it even more difficult for cessation services to intervene.

In Ireland, the Waterford Institute of Technology ran a small three month SNP-based intervention with homeless people who were accessing services. The researchers faced a number of challenges over the four-week period of the study, including that several participants were simply too ill to attend. But many of those who attended had never tried to quit before; some reduced smoking by more than 50% and as one participant remarked, "It's really helped me financially. It's helped my health. I can breathe better".[273]

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While there are millions of smokers in the poorest countries who are unable to access SNP, there are substantial numbers of others in all parts of the world struggling with marginalisation and discrimination because of ethnicity, gender and gender identification, mental health and substance use problems in the community, on the streets or in prison. For all these reasons which often combine and overlap, smoking prevalence is substantially higher than in the general population. They would clearly benefit from using SNP but are denied access through an increasingly prohibitionist environment which shows little compassion for those most in need. This is exacerbated by the lack of affordable products.

Yet, there are ways of moving forward where THR can become part of the stated WHO drive to tackle the smoking epidemic. But it demands THR being regarded as an opportunity rather than a threat and an end to anti-nicotine theology masquerading as public health. In the final chapter we suggest what those ways forward might be.

271 Dawkins, L. et al. (2019). A cross sectional survey of smoking characteristics and quitting behaviour from a sample of homeless adults in Great Britain. *Addictive Behaviors*, 95, 35–40. https://doi.org/10.1016/j.addbeh.2019.02.020

272 Matthews, C. (2019, March 5). Smoking and the Homeless: There is Hope. *Vaping Daily*. https://vapingdaily.com/support/homeless-community/

273 Scheibein, F. (2019, June 14). *A 3-month ENDS-based intervention with people accessing Irish homeless services: efficacy, challenges and opportunities*. Global Forum on Nicotine, Warsaw. https://gfn.net.co/downloads/2019/presentations/Florian_Scheibein.pdf

Chapter 8
Burning issues: conclusions and recommendations

This report has focused on THR and the benefits to public and individual health of having available, affordable, appropriate and acceptable safer alternatives to combustible tobacco products. It also focuses on the rights of smokers who need the opportunity to switch from smoking and those who have chosen safer alternatives.

Image: Andrii on Adobe Stock

1.1B SMOKERS

68M VAPERS

20M HTP USERS

10M US Smokeless and Snus

= 10 million people

The way forward

For the first time there is now a wider range of positive inducements for people to switch from smoking, rather than just disincentives. THR, through SNP, offers an unprecedented exit strategy that has been shown to be acceptable to smokers and at minimal cost to governments.

Aspirations aside, the reality is that tobacco control could only ever help to reduce harm, so the case for harm reduction has always been inherent in the mission statement for tobacco control: except now there is a real-world opportunity to add enormous heft to beneficial public health outcomes.

Image: Vagengeym on Adobe Stock

Conclusions

» Nearly 8 million people die from smoking-related diseases every year.

» Eighty per cent of the world's smokers live in LMIC, but have the least access to affordable SNP.

» A projected one billion people will die from smoking-related diseases by 2100.

» Smoking rates have been falling in more affluent countries for decades, but rates of decline are slowing.

» The global number of smokers has remained unchanged at 1.1 billion since the year 2000, and in some poorer countries this is set to rise due to population growth.

» The immediate way to reduce smoking-related deaths is to focus on current smokers.

» The evidence for SNP demonstrates that they are substantially safer than combustible tobacco, both for smokers and by-standers, and contribute to helping those wishing to stop smoking.

» The adoption of SNP has been consumer-driven with nil, or minimal, cost to governments.

» SNP have the potential to substantially reduce the global toll of death and disease from smoking, and to effect a global public health revolution.

» Progress in the adoption of SNP has been slow. We estimate 98 million people globally use SNP – including 68 million vapers – amounting to only nine per 100 smokers (fewer in LMIC). There is an urgent need to scale up tobacco harm reduction.

» Many well-funded national and international NGOs, public health agencies, and multi-lateral organisations incorrectly view THR as a threat rather than as an opportunity.

» Many US and US-funded organisations have manufactured panics about young people and vaping, about flavours and the outbreak of lung disease, overshadowing the real public health challenge, which is to persuade adult smokers to switch.

» The near-monopoly on international tobacco control funding by US-based foundations – philanthrocapitalism – has distorted international and national responses to smoking. Donor interests often exclude other policy options, producing a hidden but negative impact on health policies, particularly in LMIC.

» The increasingly prohibitionist emphasis risks many consequences, including that current smokers may decide not to switch, current users of SNP may go back to smoking, and the growth of unregulated and potentially unsafe products.

» There continues to be much poorly conducted research and science, which is then spun with an anti-THR message.

» The WHO's MPOWER initiative alone will be insufficient in hastening an end to smoking – the weakest area of achievement is 'O' – offering help – which is also the most expensive for governments.

» Harm reduction is embedded in nearly every field of the WHO's work except tobacco.

» By denying the role of THR, the WHO is working against the principles and practices enshrined in its own pledges for global health promotion and in international conventions relevant to the right to health, including in Article 1 (d) of the FCTC.

» Richer countries have been the main beneficiaries of THR. Many LMIC are left behind, through a combination of prohibitionist policies and the unavailability of appropriate, acceptable and affordable alternatives to combustible tobacco.

» Those most affected by tobacco control policies have been stigmatised and excluded from the policy conversation. Good public health engages affected populations. The slogan "nothing about us without us" is central to THR, as it is to any field in public health.

Recommendations

1. The primary aim of tobacco control should be to offer current smokers suitable exit strategies. The current predicted toll from smoking can only be averted by hastening a switch from smoking by established smokers.

2. Harm reduction should be properly defined by parties to the FCTC to sit alongside demand and supply reduction. It should be applied universally with no person, group, or community being excluded.

3. The WHO must play a lead role in encouraging FCTC signatories to take a more balanced view of the potential for SNP to help encourage a switch away from combustible products. The current interpretation of Article 5.3 of the FCTC is stifling open debate on the merits of SNP. A new and inclusive approach is required, engaging with all stakeholders with no exceptions, to evaluate the merits of new technologies and products, based on scientific principles rather than ideology.

4. Access to SNP should be a right for all potential beneficiaries irrespective of gender, race, social or economic circumstances.

5. Consumer wellbeing should be at the centre of international planning and policy.

6. The Framework Convention Alliance of NGOs should actively engage with the widest range of THR-focused NGOs, including consumer advocacy organisations.

7. Companies making SNP should strive to reach the largest number of smokers globally with appropriate and affordable products.

8. The role of government should be to hasten the switch from smoking, rather than to place obstacles in the way of those who wish to use SNP.

9. No action should be taken which has the consequence of favouring smoking over SNP, such as making SNP harder to obtain and use than cigarettes, or through unfavourable pricing (e.g. through taxes).

10. All those in positions to formulate policy on SNP should take account of the body of current evidence, rather than opting for off-the-shelf recommendations from multi-lateral and philanthropic organisations.

11. Governments should ensure consumer safety in relation to SNP, based on safety standards available through international, regional and national bodies.

12. Smokers have the right to evidence-based information about the potential benefits of switching to SNP.

13. SNP should be controlled and regulated as consumer products, and consumers need to be assured of the quality of the products they are using.

14. Having a choice of flavours in SNP is an important aspect of the decision to switch away from smoking and to avoid relapse. Banning flavours is counter-productive to positive public health outcomes.

15. There is no identified risk of 'passive vaping' to bystanders. Public health communication should explain that vaping is not smoking, and ultimately the decision to control vaping in particular locations should be left to individual organisations and businesses, rather than through blanket prohibition by government bodies.

And finally...

The two years since the last edition of this report has been a very difficult time for THR.

The estimated 1.1 billion smokers around the world deserve a better deal and better options. We need to hasten the demise of combustibles and encourage the use of safer non-combustible ways of using nicotine. Evidence from several countries shows that the availability of SNP helps people to switch from smoking.

Globally, progress is slow and those using SNP are still a small fraction of those who smoke. Vaping products have only been on the market for about 12 years and HTP much less, although snus use goes back centuries. Historically, changes in nicotine consumption take some decades. The last disruptive innovation was the invention of the tobacco rolling machine back in the 1880s, but it took around 60 years for the machine-rolled cigarette to oust most other forms of tobacco use in richer countries.

However, we can't wait 60 years. We know that SNP are just that – safer than getting nicotine by burning tobacco. We know that people want to use these products. We have proof from many countries that THR works.

The obstacles are rich foundations with a myopic view of tobacco control, and international organisations wedded to a narrow view of what can be done. There's too much fear, hatred and vested interest in this field. These organisations are rapidly finding themselves on the wrong side of history. There needs to be much more ambition about what can be done, along with a healthy dose of compassion.

During the 1980s, public health policies broadened in scope beyond the control of infectious diseases, to wider considerations of prevention through health promotion. In November 1986, the WHO convened the First International Conference on Health Promotion, held in Ottawa, Canada. From that emerged a five-page document called the Ottawa Charter, which defined health promotion,

> *"as the process of enabling people to increase control over, and to improve, their health".*

It went on to highlight that,

> *"Health promotion focuses on achieving equity in health. Health promotion action aims at reducing differences in current health status and ensuring equal opportunities and resources...People cannot achieve their fullest health potential unless they are able to take control of those things which determine their health".*

Pledges made by the participants in the Conference included:

» *"to counteract the pressures towards harmful products".*
» *"to respond to the health gap within and between societies, and to tackle the inequities in health produced by the rules and practices of these societies".*
» *"to acknowledge people as the main health resource, to support and enable them to keep themselves, their families and friends healthy".*

Tobacco harm reduction is good public health and health promotion, starting with the people who matter: smokers and those who have chosen alternatives. It's change driven from community level upwards – because it's people who do harm reduction, not experts.

Annex
Estimation of the global number of vapers

Introduction

Estimates of the prevalence of vaping are critical to measuring the uptake and coverage of THR. However, information on the prevalence of vaping is still scarce in many countries.

WHO promotes the MPOWER tobacco control programme, the first letter of which refers to Monitoring. One of the key points of this is to collect up-to-date information on issues related to the use of tobacco and related products. Unfortunately, in reality this is a very difficult task for many countries due to costs. Collecting information about the value of a particular characteristic in a given population requires a representative survey based on a random sample. Such surveys are expensive.

Market data are available within companies and from market research and analysis companies such as EuroMonitor. However there is an unclear relationship between market size – by value or units sold – and the prevalence of vaping in the population.

Data availability

We have found information on the prevalence of vaping from 49 countries. There are two publicly-available international research programmes and eight national programmes on tobacco use and vaping.

The international research from which we collect data is: *The Global Adult Tobacco Survey* (GATS),[274] last conducted in 2017, providing data on six countries (there are 25 of them in the study, but we used only six due to outdated surveys or not covering the subject of e-cigarettes); and the Special Eurobarometer on *Attitudes of Europeans towards tobacco and electronic cigarettes*[275] from the European Commission, last conducted in 2017, gathering data from 28 countries.

There are also *International Tobacco Control Surveys*[276] in 29 countries with data on e-cigarettes in six countries but we did not use it due to methodological issues (ie use of non-probabilistic samples).

National surveys on tobacco use and vaping (or at least having some information on this topic) include for example:

» *National Drug Strategy Household Survey 2019* (Australia).[277]
» *Healthy Ireland Survey* 2017.[278]

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[274] *WHO | Global Adult Tobacco Survey (GATS).* (n.d.). WHO; World Health Organization. Retrieved 3 August 2020, from http://www.who.int/tobacco/surveillance/survey/gats/en/

[275] *Special Eurobarometer 458: Attitudes of Europeans towards tobacco and electronic cigarettes – European Union Open Data Portal.* (n.d.). Retrieved 23 June 2020, from https://data.europa.eu/euodp/en/data/dataset/S2146_87_1_458_ENG

[276] Department of Psychology, University of Waterloo. (n.d.). *Surveys – ITC Project.* International Tobacco Control (ITC) Policy Evaluation Project. Retrieved 3 August 2020, from https://itcproject.org/surveys/

[277] *National Drug Strategy Household Survey 2019.* (n.d.). Australian Institute of Health and Welfare. Retrieved 3 August 2020, from https://www.aihw.gov.au/about-our-data/our-data-collections/national-drug-strategy-household-survey/2019-ndshs

[278] *Healthy Ireland Survey 2017.* (n.d.). Retrieved 3 August 2020, from https://www.gov.ie/en/publication/a2e250-healthy-ireland-survey-2017/?referrer=/blog/publications/healthy-ireland-survey-2017/

» *Malaysia 2016 National E-Cigarette Survey.*[279]
» *Encuesta Nacional de Consumo de Drogas, Alcohol y Tabaco (ENCODAT 2016-2017, Mexico).*[280]
» *Use of e-cigarettes among adults in Great Britain*, *2019* (ASH UK).[281]
» *Surveys from the Office for National Statistics* (UK 2019).[282,283]
» *National Adult Tobacco Survey* (US).[284]

In addition, we have information from general surveys for seven other countries.

Surveys on vaping

Surveys
National
Eurobarometr
Global Adult Tobacco Survey
No survey
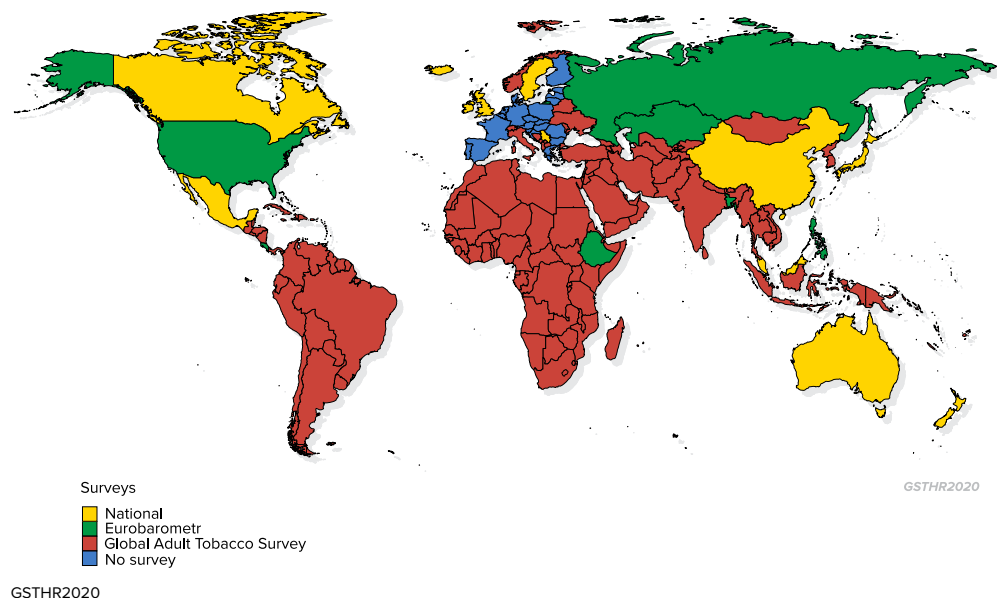
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Data were introduced in our database and maintained by the GSTHR research group. Quality controls – consisting of the continuous cooperation with regional informants around the world – are regularly performed to ensure that sources are updated, and data are introduced correctly.

Methods

Assumptions

Given that there is information for only 49 countries, the question arises as to how to estimate the prevalence of vaping in countries for which information is unavailable.

Where national data are unavailable, we have used an accepted epidemiological method of estimating country data by assumed similarity with other countries in the same region and economic condition for which data points are available. This methodology is commonly used for estimating health status in the absence of national

[279] Ab Rahman, J. et al. (2019). The Prevalence of E-Cigarette Use Among Adults in Malaysia: Findings From the 2016 National E-Cigarette Survey. *Asia Pacific Journal of Public Health*, 31, 101053951983473. https://doi.org/10.1177/1010539519834735

[280] Comisión Nacional contra las Adicciones. (n.d.). *Encuesta Nacional de Consumo de Drogas, Alcohol y Tabaco, ENCODAT 2016–2017*. gob.mx. Retrieved 3 August 2020, from http://www.gob.mx/salud%7Cconadic/acciones-y-programas/encuesta-nacional-de-consumo-de-drogas-alcohol-y-tabaco-encodat-2016-2017-136758

[281] Use of e-cigarettes among adults in Great Britain, 2019. (2019, September 2). *Action on Smoking and Health*. https://ash.org.uk/information-and-resources/fact-sheets/statistical/use-of-e-cigarettes-among-adults-in-great-britain-2019/

[282] Adult smoking habits in the UK*: 2019* (ONS Statistical Bulletin). (2020). Office for National Statistics.

[283] *E-cigarette use in England – Office for National Statistics*. (n.d.). Retrieved 3 August 2020, from https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/healthandlifeexpectancies/datasets/ecigaretteuseinengland
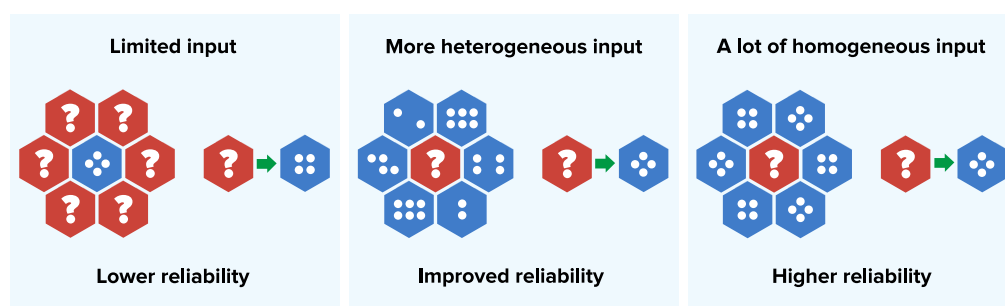
[284] CDC's Office on Smoking and Health. (2014). *Smoking and Tobacco Use; Data and Statistics; National Adult Tobacco Survey (NATS)*. Smoking and Tobacco Use. http://www.cdc.gov/tobacco/data_statistics/surveys/nats/

surveys.[285,286,287] It works in the same way as many methods used for statistical inference and analysis with incomplete data.

The main mathematical tool used for estimation was the method of average similarity.[288,289,290] It assumes that if certain characteristics in a given group of countries are similar, we can assume that these countries will also be similar in other respects. This allows us to impute unknown values of the characteristics with the average values of those characteristics in the countries where they are known.

The quality of such estimation depends on the ratio of known and unknown fractions. The more known input data we use and the more homogeneous they are, the better result we will get. Table 1 shows the relationship between amount and internal differentiation of input data and quality of estimates.

Input data and quality of estimates

Limited input	More heterogeneous input	A lot of homogeneous input
Lower reliability	Improved reliability	Higher reliability

A further issue regards the availability and relevance of data on country characteristics from which similarity between countries may be inferred. We used the WHO region, the World Bank income classification and the legal status of e-cigarettes.

The second methodological problem is that surveys are conducted in different years and are often not repeated. Most of the available data allow for the calculation of an estimate for 2018 (most of the recent studies are from 2018 or before). Therefore, the data need to be adjusted to arrive at estimates for 2020. This can be done by reference to data on market growth. Based on publicly available "Statista" analyses,[291] we can track changes in global revenues in the e-cigarette market. Assuming a linear relationship between market revenues and the number of users, we can estimate forward the global number of vapers in 2020.

This assumed relationship is unclear, as market values are affected by price and consumption patterns. Not every shift in the market affects 100 per cent of the number of users. It would be good for the quality of the projection to know what the real efficiency of the relationship between market data and the number of vapers is in the population. It can be easily calculated using the Pearson's correlation coefficient and the data where both the local market revenue and the prevalence of vapers are known.

[285] Aceijas, C. et al. (2004). Global overview of injecting drug use and HIV infection among injecting drug users. *AIDS*, 18(17), 2295–2303.

[286] Dawood, F. S. et al. (2012). Estimated global mortality associated with the first 12 months of 2009 pandemic influenza A H1N1 virus circulation: a modelling study. *The Lancet Infectious Diseases*, 12(9), 687–695. https://doi.org/10.1016/S1473-3099(12)70121-4

[287] Verity, R. et al. (2020). Estimates of the severity of coronavirus disease 2019: a model-based analysis. *The Lancet Infectious Diseases*, 20(6), 669–677. https://doi.org/10.1016/S1473-3099(20)30243-7

[288] Little, Roderick J A, & Rubin, D. B. (2002). *Statistical Analysis with Missing Data* (2nd ed.). A Wiley-Interscience publication.

[289] Little, R J A. (1997). Biostatistical Analysis With Missing Data. In P. Armitage & T. Colton (Eds.), *Encyclopedia of Biostatistics*. Wiley.

[290] Orchard, T., & Woodbury, M. A. (1972). A Missing Information Principle: Theory and Applications. *Proc. 6th Berkeley Symposium on Math. Statist. and Prob.*, 1, 697–715.

[291] *E-Cigarettes – worldwide | Statista Market Forecast (adjusted for expected impact of COVID-19)*. (2020, May). Statista. https://www.statista.com/outlook/50040000/100/e-cigarettes/worldwide

Estimation methods

Based on the available information, we calculated the average prevalence of vaping for the WHO region, World Bank income classifications and legal status of the sale of e-cigarettes. Unfortunately, as we could guess, some groups are very poorly represented. Low-income countries are represented only by Uganda. Uganda is also the only data point for the African region. Similarly, we have only one data point from the South East Asia region with Bangladesh and the East Mediterranean region with the United Arab Emirates.

Average prevalence of vaping by factors used in the estimation

| World Bank income classifications	N	Users (%)
High income	35	1.90
Upper middle income	11	1.21
Lower middle income	2	0.50
Low income	1	0.50
WHO regions	**N**	**Users (%)**
South-East Asia region	1	0.20
African region	1	0.50
Western Pacific region	8	1.34
European region	32	1.70
Region of the Americas	6	1.72
Eastern Mediterranean region	1	5.00
Sale	**N**	**Users (%)**
Banned	6	0.93
Allowed	40	1.75
No specific law	3	1.80

These three factors gave us four income groups, six regions and three sales statuses, which allowed us to separate 72 subgroups. For each of the groups the average prevalence of vaping was calculated. These 72 values were used as substitutes for the prevalence figures in the countries belonging to the group. Of course, not all subgroups were represented. For the first (1) – the most detailed, three-factor – subdivision we had information for only 13 subgroups, which allowed us to calculate estimates for 83 countries.

For the other countries, we had to use a two-factor breakdown covering all pairs of these three factors. A second (2) split was made on the basis of income groups and sales status, which gave us eight information cells covering 161 countries, a third (3) was made on the basis of income groups and regions with 10 information cells covering 142 countries and a fourth (4) was made on the basis of regions and sales status with nine information cells covering 102 countries. Last (5) subdivision was based only based on one income groups factor.

The results of the calculations have been placed successively in the blanks remaining after the previous step. This means that the countries remaining without an estimated value after the first step have been assigned the values generated in the second step. In the third step we filled in the missing values remaining after the second step and in the fourth step remaining after the third step. All remaining gaps were filled with the fifth step.

We started with 49 known countries. The first step increased this number to 83, the next to 161, next to 190, the fourth one gave us only three more countries, increasing the number of countries to 193, and the fifth to 198. There were still three countries left. We attributed the average value obtained from all known countries to these countries.

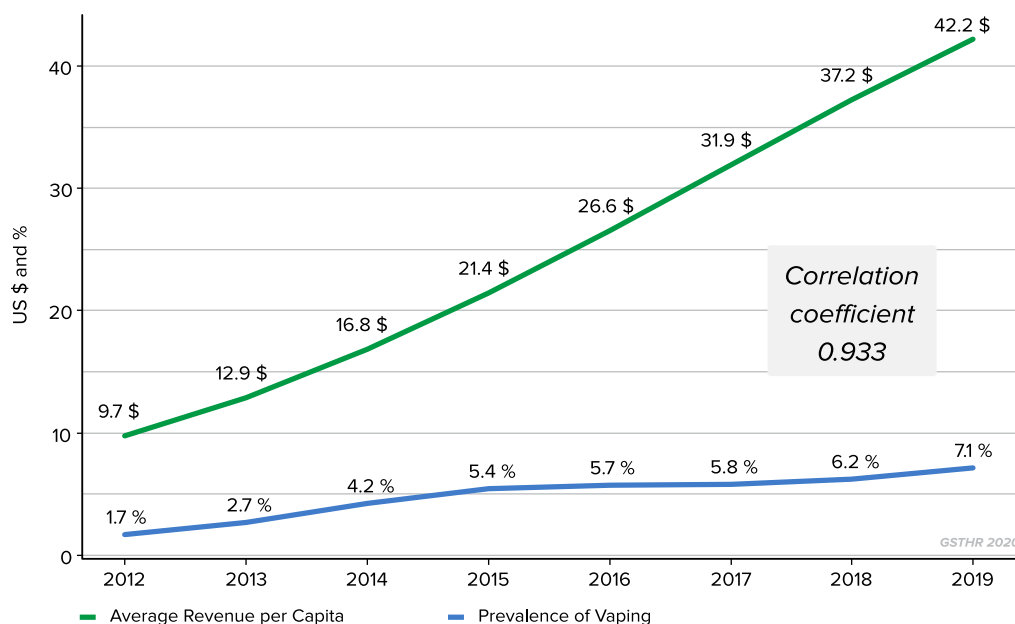**Information growth at subsequent levels of the estimation process**
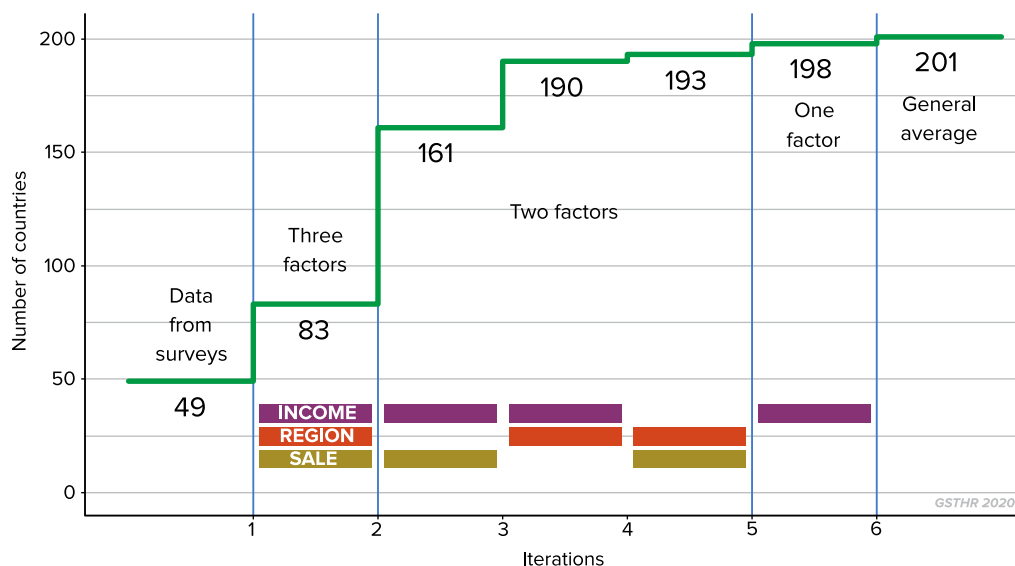
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The number of vapers was calculated by taking as the denominator the total adult population (over 15 years old) obtained from the UN database for 2018.[292]

Adjustment of the estimate for market value changes between 2018 and 2020

Correlation between average revenue per capita and prevalence of vaping in UK

E-cigarette use in England – Office for National Statistics. (n.d.). Retrieved 3 August 2020, from https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/healthandlifeexpectancies/datasets/ecigaretteuseinengland
E-Cigarettes – worldwide | Statista Market Forecast (adjusted for expected impact of COVID-19). (2020, May). Statista. https://www.statista.com/outlook/50040000/100/e-cigarettes/worldwide

Given the time lapse between when surveys were undertaken and 2020, it is necessary to estimate subsequent growth. The question is, what is the relationship between market growth and changes in vaping prevalence? We have information on this for the UK for the period 2011 to 2019. We have used market revenues per capita to

[292] Department of Economic and Social Affairs (Ed.). (2019). *World Population Prospects 2019* (Online Edition Rev. 1.; Population Division). United Nations. https://population.un.org/wpp/Download/Standard/Population/

avoid distortions related to population changes. As we can see in Figure 1, both trends were characterised by steady growth. The correlation between both time series was very strong. On the basis of this analysis, it can be concluded that the changes in the revenues from the vape market have influenced the prevalence of vaping products with 93 per cent efficiency. Then we assumed that this relationship is similar globally.

Results

The number of vapers in the 49 countries from which the survey data are derived is 40.3 million. We estimate that 17.8 million vapers live in the remaining 152 countries. This gives a total of 58.1 million vapers worldwide in 2018.

Main results of the estimate for 2018

Global number of vapers	
40,334,650	people in countries with real data from surveys
17,772,956	people in countries with estimation
58,107,606	Total

2.1 million vapers live in low income countries, 7.8 million in lower middle income countries, 19 million in upper middle income countries and 29.3 million in high income countries.

Estimated number of vapers by income groups for 2018

Income groups	Countries (N)	Vapers (N)
Low income	31	2,115,585
Lower middle income	47	7,760,169
Upper middle income	54	18,959,299
High income	54	29,269,384
Unknown	1	3,169

4.1 million vapers live in the African region, 4.2 million in the Eastern Mediterranean region, 4.6 million in the South-East Asia region, 11.2 million in the Western Pacific region, 15.3 million in the European region and 18.7 million in the region of the Americas.

Estimated number of vapers by WHO regions for 2018

WHO regions	Countries (N)	Vapers (N)
African region	47	4,107,918
Eastern Mediterranean region	21	4,199,293
South-East Asia region	11	4,554,551
Western Pacific region	23	11,150,297
European region	50	15,345,345
Region of the Americas	33	18,741,095
Unknown	2	9,107

38.6 million of vapers live in countries where sale of nicotine vaping products is allowed, 9.5 million in countries where sale of nicotine vaping products is banned and 10 million in countries where there is no specific law.

Estimated number of vapers by legal status of nicotine vaping products for 2018

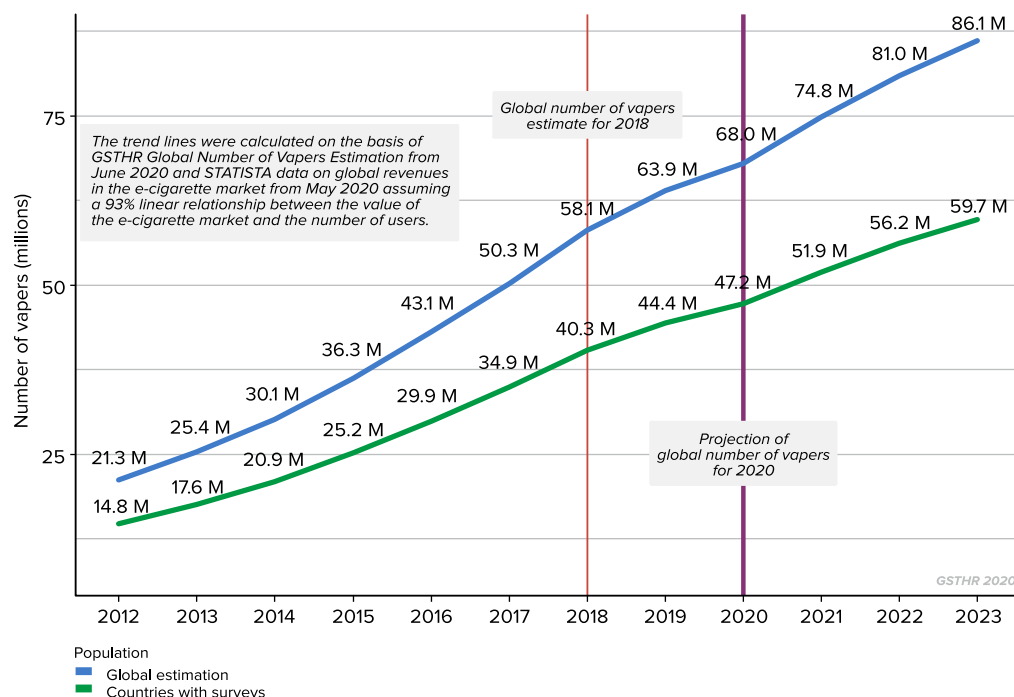| Legal status	Countries (N)	Vapers (N)
Allowed	72	38,648,243
Banned	36	9,458,630
No specific law	79	10,000,733

The projection for year 2020 was made on the basis of information from the *E-Cigarettes Worldwide Statista Market Forecast.*[293] The global number of vapers estimate was fitted to revenue data at the 2018 time point (meaning revenue data from 2018 was directly paired with estimated number of vapers). In other words, the market trend was zeroed (calibrated) at 2018. The proportions series – centred at 2018 – was adjusted with the mentioned above coefficient of the correlation between market revenue and number of vapers.

Revenue trend in percents centered at 2018

2012	2013	2014	2015	2016	2017	**2018**	2019	**2020**	2021	2022	2023
37%	44%	52%	62%	74%	87%	**100%**	110%	**117%**	129%	139%	148%

Multiplying subsequent proportions by the estimated global number of vapers, we have given projections of this number for other years. For the year 2020, the projection is 68 million vapers globally.

Estimated trends in the worldwide number of vapers (adjusted)

The trend lines were calculated on the basis of GSTHR Global Number of Vapers Estimation from June 2020 and STATISTA data on global revenues in the e-cigarette market from May 2020 assuming a 93% linear relationship between the value of the e-cigarette market and the number of users.

Global number of vapers estimate for 2018

Projection of global number of vapers for 2020

Number of vapers (millions)

Population
— Global estimation
— Countries with surveys

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E-Cigarettes – worldwide | Statista Market Forecast (adjusted for expected impact of COVID-19). (2020, May). Statista. https://www.statista.com/outlook/50040000/100/e-cigarettes/worldwide

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[293] *E-Cigarettes – worldwide | Statista Market Forecast (adjusted for expected impact of COVID-19).* (2020, May). Statista. https://www.statista.com/outlook/50040000/100/e-cigarettes/worldwide

Discussion

We estimate that there are approximately 68 million nicotine vaping product users worldwide. However, this estimate should be treated with caution, as there is great uncertainty about some of the individual country estimates, and for 152 countries and territories data were missing. There is also variation in survey definitions of vaping. It is obvious from the data collected and assessed in our database that the available information is often of poor quality – survey samples are not numerous enough to provide sufficient precision to measure such small parts of the population. The sampling method of many studies is not probabilistic, which makes it impossible to generalise the measured values correctly per population. It is well known that monitoring risk behaviours in hidden populations is not straightforward. However, efforts to improve the accuracy of the information systems should be encouraged.