SAVING LIVES

AN ADVOCATE'S GUIDE TO TOBACCO HARM REDUCTION

PART OF THE
2020 AHRA ADVOCACY PACK

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Tobacco Harm Reduction 2020 is an online, free-content publication to raise awareness and support tobacco harm reduction (THR) as a means to prevent tobacco-related disease and premature death in adult smokers.

Our request to readers is two-fold: first, to challenge the scientific arguments in this book, and with us help strengthen evidence-based policy. Secondly, that this content is used to empathetically support persons who smoke, who cannot or will not quit. Encourage them to switch from the most harmful cigarettes to less harmful, non-combustible nicotine-based products.

This publication is dedicated to the alliance of vapers worldwide.

THR 2020 was written collaboratively by multiple authors, for the Africa Harm Reduction Alliance and supported by Delon Human and Health Diplomats.

CHAPTER 1

Tobacco Harm Reduction: An Introduction

The World Health Organization (WHO) states that tobacco products have caused 100 million deaths in the 20th century alone. Every year, there are seven million tobacco-related deaths worldwide, of which 80% are tobacco users in the world's low-and middle-income countries. If current trends persist, another BILLION people are predicted to die from tobacco-related diseases during the 21st century.[1]

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SMOKE KILLS, NOT THE NICOTINE

Although nicotine is the major addictive substance in tobacco products it is also, unfairly, given the blame for the disease and death caused by tobacco products.

"It is the smoke that kills, not the nicotine" [1] is a refrain that you will often read in this book, because this erroneous belief is an obstacle to reducing the harm caused by tobacco products.

It is so important to understand that the inhalation of toxicant-filled smoke, – produced by combustible tobacco products (mostly cigarettes) – is overwhelmingly responsible for tobacco-related disease and premature deaths. There is a common belief that all tobacco products are the same, that the risk in smoking a cigarette is the same as from chewing tobacco, using Swedish style "snus" or even vaping an E-cigarette.

Yet, science does not support this belief. The many tobacco and nicotine products available to consumers vary widely in their risk and functionality.

This continuum of risk needs to be researched, clarified and, most importantly, communicated to consumers. Only then will individuals be able to make an informed choice and use nicotine more wisely.

SMOKE-FREE (NON-COMBUSTIBLE), NICOTINE-BASED PRODUCTS ARE PART OF THE ANSWER, NOT THE PROBLEM

The field of tobacco harm reduction (THR) can offer a respite to smokers who are unwilling or unable to quit smoking. Several new categories of non-combustible, nicotine-based alternative nicotine delivery systems are substantially less harmful than cigarettes.

THR science and products provide an evidence-based method for smokers to reduce the harm caused by their use of tobacco. It does this by incrementally substituting less hazardous products for those more likely to cause harm to their bodies.

> "The field of tobacco harm reduction (THR) can offer a respite to smokers who are unwilling or unable to quit smoking."

Unfortunately, the public health community has been so intent on creating a "tobacco-free" world, that THR has simply not been given a chance. In many ways, this is the elephant in the room for health professionals – a truth that most know but are reticent to discuss.

HEALTH PROFESSIONALS' CRITICAL ROLE IN REDUCING TOBACCO-RELATED HARM

Another key element in the THR story is the role of health professionals, especially physicians. Health professionals play a vital role in the health related decision-making processes of their patients. Moreover, they care for and advise many tobacco consumers.

This book is primarily aimed at health professionals and the active and passive smokers they care for. Patients and their physicians have a relationship that differs from that in any other profession. In a world of information overload, patients turn to their physicians to provide them with reliable and science-based advice. The family physician also often becomes a confidante and friend. The advice physicians provide to smokers most frequently is to stop smoking altogether, which of course, is sound advice.

However, with more than one billion people smoking worldwide, it is unlikely that every patient who visits their medical practitioner will value or heed a straightforward quitting message.

COMMUNICATING TOBACCO HARM REDUCTION

What if physicians or other attending health professionals also communicated the benefit of harm reduction to smokers? Are we not effectively harming patients by neglecting to tell them about other potential options that are available to help them to break their habit?

The most famous medical dictum enshrined in the Hippocratic Oath, **"First, do no harm"**, is a vital reminder of our responsibility towards our patients. Yes, the health of the society we live in is important, but it is also imperative that every health professional serves the best interests of each individual patient for whom they are providing care.

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> The famous dictum enshrined in the Hippocratic Oath, 'First, do no harm', is a haunting reminder of our responsibility towards our patients. It is imperative that we serve the best interests of each individual patient for whom we are providing care."

If that patient happens to be an inveterate smoker of 30 to 60 cigarettes a day who has no intention or capacity to quit, are we not harming them by refraining from telling them about the concept of tobacco harm reduction and the different products that can be used? This is one of the ethical issues that this book will cover.

IMPRECISE HEALTH COMMUNICATION REGARDING TOBACCO PRODUCTS

A major obstacle for tobacco harm reduction is the imprecise use of language and inaccurate information disseminated to consumers of tobacco and nicotine products. The World Health Organization (WHO) has consistently advocated "All tobacco kills" or "Tobacco, deadly in any form or disguise".

It is intended to amplify the tobacco cessation or quitting message, which is laudable, but it also ignores other health promotion messages that could be communicated to both consumers and health professionals. Often, this leads to further bad choices.

Imagine if we used this type of non-specific health and risk communication during the current COVID-19 pandemic. Just as not all viruses are the same, there should be a clear distinction made between the various categories of tobacco and nicotine products, and their relative risk communicated to policymakers and consumers.

DON'T BLOCK THE FIRE ESCAPE

Health practitioners practise harm reduction every day. Consumers and patients are provided with simple health prevention advice on how to avoid disease or reduce harm. Mothers are advised to sterilise bottles used for feeding infants, youngsters always to wear helmets when they ride bicycles, the use of condoms is encouraged for "safer" sex and road users are warned about the consequences of the not using safety belts. Some of these recommendations are even backed up by law. Yet when it comes to tobacco, it seems as if the public health community is only singing the abstinence tune.

Consider a fire breaking out in a hall containing 1.1 billion people. Officials block the fire escape doors because they cannot guarantee safety outside.

This analogy is a rather accurate description of how tobacco control has erred in its approach to nicotine and harm reduction. Here, the people represent the current global smoking population of 1.1 billion people who choose to smoke cigarettes, exposing themselves to fire every day. The well-meaning officials represent the public health leadership who warn the crowd not to leave the hall, because the relative safety of the situation outside/non-combustible nicotine products has not been proven. Unfortunately, this refrain of "not enough research" also has unintended and deadly consequences.

KEY DETERMINANTS FOR GROWTH IN TOBACCO HARM REDUCTION

Tobacco harm reduction is, and will always be, about shifting tobacco users down the risk continuum to the least harmful products or as an aid to cessation. At this point, THR has not been universally adopted, either by public health, or by the consumer in the street. To some extent, this fact results from the imbalance of four key factors:

SCIENCE:
There has been an overemphasis on the science of combustible tobacco products and a lack of emphasis on the science of the safety or risks, functionality and efficacy of non-combustible, nicotine-based products

POLICY:
(Combustible) tobacco control has dominated all forms of regulation, especially since the adoption of the Framework Convention on Tobacco Control (FCTC)

CONSUMERS:
The (tobacco) abstinence-only message has caused confusion among consumers. Greater emphasis should be placed on consumer understanding, gaining acceptance of the reduced harm concept and consequential use of new nicotine products

PRODUCTS:
The most unhelpful element of tobacco control is the lack of differentiation between the risks of different types of tobacco and nicotine products. Placing a greater emphasis on the development of innovative new nicotine products that act faster and more effectively, would greatly benefit the growth of THR.

Figure 1: Different Worlds: Public Health & Tobacco and Nicotine Industries

DIFFERENT WORLDS.

One reason why the public health community and the tobacco industry have never seen eye-to-eye, is that they occupy different worlds and have very little understanding of each other. The tobacco industry, like most fast-moving consumer goods (FMCG) companies, thinks in consumer-centric terms and is masterful in developing and marketing products.

On the other hand, the public health community dwells in the world of scientific investigation and evidence gathering. It then uses this scientific evidence to develop sound public policy. Because of these different worlds, there is an imbalance in the development of tobacco and nicotine policy, science, consumer and products.

If only the two communities would consider the other's point of view, there could be an opportunity to apply nicotine and THR more wisely in society.

> "Tobacco harm reduction is, and will always be about shifting tobacco users down the risk continuum to the least harmful products or as an aid to cessation."

CONSUMERS – THE UNHEARD VOICES IN THE TOBACCO HARM REDUCTION DEBATE

For decades, the tobacco control debate has raged on in a most paternalistic way. Consumers have not been adequately consulted on their views on tobacco and nicotine use, such as why they smoke or vape, if and how they want to quit and what their needs are. Instead, this book will unashamedly reach out and publish the views of consumers, since it is essential to record their opinions, experiences and potential roles in tobacco harm reduction. Consumers can play a major role in the development of clear health and risk communication on alternative ways to use nicotine and reduce harm.

2020 AND 2021 – TIME FOR CRUCIAL POLICY DECISIONS ON TOBACCO HARM REDUCTION

2020 and 2021 will be an immensely important period for tobacco control and harm reduction. During 2020, the European Union will review the Tobacco Product Directive (TPD). In addition, the WHO FCTC parties will host their next Conference of the Parties (COP9) in the Netherlands in November 2021 (World Forum The Hague, 2021).[3] As tobacco harm reduction has long been the orphan of the FCTC, this will be an ideal opportunity to expand the FCTC with more precise policy recommendations to member states on tobacco harm reduction.

OUTLINE OF THE BOOK

The book is available online in a clickable PDF format to facilitate downloading of chapters or any sections of the book. We have developed this book as part of an open source knowledge repository on tobacco harm reduction (THR). Its primary audience is tobacco and nicotine consumers and those in the harm reduction community involved in supporting smokers to quit or switch to less harmful nicotine products.

The book will mention aspects relating to policies, science, consumers and products in this field. In addition, it will disclose the findings of 2020 research on consumer perceptions about vaping (electronic cigarettes) and heated tobacco products. In this way, we hope to work together to prevent tobacco-related disease and premature death.

WHAT THIS BOOK IS NOT ABOUT

It is not about cigarettes. Most writing about tobacco control tends to focus on combustible tobacco control, specifically cigarettes. This book will deliberately take a different route and focus instead, on non-combustible, nicotine-based delivery devices, many of which are compatible with tobacco harm reduction.

It is not about the past, but the future. There are armies of researchers scouring through the internal papers of tobacco and nicotine companies to find inconsistencies, untruths and foul play in their public statements made over the last decades. Typically, these findings are about historical events or misdemeanours and focus on cigarettes. This book seeks to be more future-oriented and solution seeking.

Veteran tobacco control advocates will recall how waves of "demonisation" were used as an intentional strategy to combat tobacco. First, demonise the industry, then the product and lastly, isolate the consumer. This tactic was so successful that many tobacco control advocates persist in that way of thinking and acting. It is time to advance the debate towards a civil, constructive and science-based evaluation of tobacco and nicotine POLICIES and PRODUCTS. If there were one objective all stakeholders should single-mindedly be pursuing, it is the prevention of tobacco-related disease and death - using science, proportionate policies and safer products to deliver nicotine.

> This book does not seek to demonise the tobacco or nicotine industries. Rather, it aims to shift the health profession's focus to the science needed to underpin POLICIES and PRODUCTS that can deliver nicotine with less risk to the consumer.

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CHAPTER 2

Defining Tobacco Harm Reduction

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HARM REDUCTION

WHAT IS HARM REDUCTION?

Harm reduction is a public health strategy that has been used to reduce or minimise the harm associated with a certain risky behaviour, without necessarily having to eliminate that behaviour. It therefore recognises that there will probably always be people who engage in activities that involve risk. In democratic societies, there are often trade-offs to be made. In this regard, harm reduction is a significant public health alternative to outright prohibitions and bans. Below are several examples:

- The use of condoms and other preventive measures for dealing with hiv and other sexually transmitted diseases;
- Needle exchange programmes to minimise the spread of hiv/aids and reduce disease and deaths for drug users;
- Availability of foods low in fat, cholesterol, sodium, and sugar (rather than seeking an outright prohibition or mandated reduction in these elements);
- Sex education for adolescents and condom distribution in schools to reduce teen pregnancies, rather than relying on abstinence as the only solution;
- Reducing environmental carbon emissions and chemical discharges (instead of total elimination) to control and improve air and water quality, which includes providing industry with incentives for reducing such emissions;
- Requiring the use of seatbelts and other safety requirements in motor vehicles;
- Prescribing methadone as a substitute for heroin;
- Having motorcycle helmet laws to reduce the severity of head injuries; and
- Offering designated driver programmes to reduce drunk driving.

In the past, harm reduction was mostly associated with the methods used to treat licit or illicit drug use. This is also one of the focus areas of Harm Reduction International (HRI), which defines harm reduction as “policies, programmes and practices that aim primarily to reduce the adverse health, social and economic consequences of the use of legal and illegal psychoactive drugs without necessarily reducing drug consumption. Harm reduction benefits people who use drugs, their families and the community.”[1]

WHY IS HARM REDUCTION A CONTROVERSIAL SUBJECT?

Unfortunately, harm reduction has also evoked many emotional debates and some controversy. In reality, there will always be people who engage in risky behaviour, no matter what the consequences might be to themselves or others. Those who support the principles of harm reduction seek to reduce or mitigate the health risks associated with these risky behaviours, rather than to eliminate them.

There are two sides in the debate. Nearly everyone in the public health community still advocates abstinence as the only defendable goal. Here, the underlying philosophy is that we should all work for a drug-free or tobacco-free world. In their recent study, Alderman, Dollar and Kozlowski[2] noted that public health ethics tend to emphasise social justice concerns to the exclusion of other moral perspectives that value scientific authority, professional loyalty and bodily purity. Their views emphasise the need for a greater awareness of the different emotional reactions and underlying moral motivations in the harm reduction debate.

However, the number of those that support the concept of harm reduction is growing. The pragmatists usually embrace the concept first, as they come to appreciate that for some people, abstinence is an unrealistic goal. Some individuals will always engage in risky behaviour such as smoking or using drugs, so it is preferable to try to mitigate the consequences for them and others affected by that behaviour.

One of the first principles of medical ethics coined by Hippocrates is “first, do no harm”. While many would say the Greek physician’s meaning was not: “first, do less harm”, there is clearly a moral imperative to act to reduce harm if that is the only option available. This is, after all, the principle of pain reduction in the terminally ill, where physicians use medication to alleviate suffering even when the condition is incurable. No one would suggest withholding treatment of any kind simply because a condition is untreatable.

CONFLICT BETWEEN INDIVIDUAL AND COMMUNITY INTERESTS IN HARM REDUCTION

Harm reduction highlights the frequent conflict between societal and individual interests in medical practice. Harm reduction itself can be achieved at the level of the individual and at the societal level. For example, a physician advising a patient to substitute smoking cigarettes with using a less toxic substance such as snus may result in a net decrease of harm in that patient. However, this may not necessarily achieve a net increase in benefit to society. That is because snus users will still use the product, in part, to satisfy their addiction to nicotine. Thus, what constitutes harm reduction for an individual may not necessarily result in a net decrease in harm for society overall.

If a product is only marginally less harmful, but a larger proportion of the population uses it, the result could be an increase in societal harm. If there is a significant reduction in risk, however, there is likely to be a public health benefit despite a large increase in use. In this regard, Kozlowski and colleagues[3] argue that:

> “Public health concerns should trump individual rights only when there is clear and convincing evidence of harm to society. Lacking that evidence, individual rights should prevail.”

PUBLIC HEALTH’S DEFINITION OF HARM REDUCTION

In public health, the term harm reduction (or harm minimisation) is used to denote the reduction of harmful consequences associated with a specific risky activity. It is a way of dealing with behaviour that could damage the health of the individual involved and their community. The aim of harm reduction is to improve individual and community health. Historically, harm reduction has mostly been associated with “risky activities” such as drug use, unsafe sex or driving under the influence of alcohol. This has led to the development of public policies designed to reduce the harmful consequences of these and other specific high-risk activities.

At the heart of harm reduction is an appreciation that these risky activities will probably not disappear, but that the harm that they cause can be reduced. Of course, in many cases, the ideal is abstinence or the complete avoidance of a certain, risky behaviour. However, in the absence of such a preferred situation, one can use a more pragmatic approach to reduce harm. For example, no government will seek to ban skiing or bike riding, but it does recommend the use of helmets or even make it compulsory.

HARM REDUCTION AND HEALTH PROFESSIONALS

Harm reduction has always been a part of the training and practice of health professionals. Scrubbing hands before surgical procedures and ensuring that sharp objects are properly disposed of are everyday examples of harm reduction. When they advise patients to lose weight or use alcohol in a responsible manner, surely this is also harm reduction in practice? Even prescribing medicine is a form of harm reduction.

HAND WASHING AS HARM REDUCTION

During the Covid-19 pandemic, hand washing has become a worldwide example of harm reduction. Everyone understands that thorough hand washing minimises the chances of catching or inadvertently transmitting the virus. Modern health professionals are trained to wash their hands thoroughly before or after contact with their patients or any unclean surfaces. Ironically, until the late 19th century, health leaders scorned those advocates of hand washing and, figuratively, washed their own hands of the consequences for public and individual health. Incredibly, resistance to hand washing as a harm reduction principle continued late into the 19th century. Louis Pasteur, founder of the germ theory, complained in 1879 that physicians were to blame for carrying deadly microbes from sick women to healthy ones. Pasteur went on to become a tireless advocate of hygiene, but even his efforts initially evoked scepticism.

Now, hand washing is a standard operating procedure in medicine. According to the United States Centers for Disease Control and Prevention (CDC), “Handwashing is the single most important means of preventing the spread of infection.”

In addition, simple hand washing with soap is now recognised to be among the most effective and inexpensive ways to prevent transmission of diarrheal diseases and pneumonia, which are together responsible for the majority of child deaths.

Every year, more than 3.5 million children die before their fifth birthday because of diarrhoea and pneumonia. The World Health Organization (WHO) now devotes more time and resources to prevention in this area, with initiatives such as a *“Global Handwashing Day”*. [4] [5] [6]

Harm reduction highlights the frequent conflict between societal and individual interests in medical practice. Harm reduction itself can be achieved at the level of the individual and at the societal level.

PRINCIPLES OF HARM REDUCTION

Do not solely focus on abstinence

- Harm reduction supports all those that seek to moderate or reduce their substance use. This means it neither excludes nor presumes a goal of abstinence; and
- Short-term abstinence-oriented treatments have low success rates. For example, in the case of opiate users, such treatments have high rates of post-treatment overdose.

Focus on risk and harm

- Provide responses that reduce risk, thereby reducing or avoiding harm;
- Risk reduction interventions usually focus on the user's behaviour;
- Recognise that an individual's ability to change behaviour is also influenced by the norms held in common by fellow users as well as the attitudes and views of the wider community; and
- Harm reduction interventions may target individuals, communities and the wider society.

Be pragmatic

- Accept that the use of drugs (and indeed, other harmful substances such as tobacco and alcohol) is a common and enduring feature of human experience;
- Acknowledge that, while carrying risks, using substances such as drugs, alcohol and tobacco provide users with benefits that must be taken into account if responses to their use are to be effective; and
- Harm reduction recognises that containing and reducing harm related to drugs, alcohol or tobacco is a more viable option than efforts to eliminate their use.

Seek to maximise the range of intervention options that are available

- Engage in a process of identifying, measuring, and assessing the relative importance of substance-related harms. Assess the relative costs and benefits in trying to reduce them.

Respect humanist values

- Accept the user's decision to use drugs/tobacco/alcohol;
- Make no moral judgement supporting or condemning the use;
- Respect the dignity and rights of the user. Endeavour to offer "user-friendly" services; and
- Recognise that, for many, dependent use is a long-term aspect of their lives and that actions to address their addiction have to recognise this.

Prioritise goals

- Harm reduction responses to substance use (e.g. drugs, alcohol or tobacco) include the notion of a hierarchy of goals. The primary focus is on proactively engaging individuals and targeting groups and communities to address their most compelling needs through providing accessible and user-friendly services; and
- Achieving the most important and realistic goals is an essential first step toward either risk-free use or abstinence.

THE FUTURE OF HARM REDUCTION

The need for and benefits of harm reduction practices and policies seem compelling. However, the level of resistance in the public health community to harm reduction in the fields of tobacco, alcohol and drugs is alarming. Some of the most prominent leaders in health care are still washing their hands in innocence, (or possibly even ignorance), of the benefits that harm reduction can offer to individuals and communities in these fields.

Yet, it is encouraging to see a distinct shift in harm reduction – from a morals-based discussion to its science. This will ultimately provide a more robust framework for discussion and evaluation of risky behaviours and products, and how best to manage these risks in our modern society.

The sustainability of harm reduction as a policy will also depend on how evidence validates its benefits for the individual and society.

What cannot be tolerated however, is an ongoing indifference to the potential benefits of harm reduction, especially in the field of tobacco. If there is clear scientific evidence that individual and societal benefit is gained from harm reduction, this should be fully embraced.

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TOBACCO CONTROL STRATEGY

To better understand how harm reduction may be applied in tobacco control, it is first useful to reassess what tobacco control is and how it differs from harm reduction.

For five decades, policymakers have been working to control the burden of tobacco-related diseases. Such tobacco control strategies should focus on reducing premature death and serious harms like cancer, cardiovascular and respiratory disease as quickly as possible. Therefore, the most effective tobacco control strategy has four main elements:

1. To provide strong incentives not to start smoking
2. To motivate and help people to quit smoking
3. To reduce harm to non-smokers arising from exposure to toxins in second hand smoke
4. To reduce harm to those who continue to use nicotine

THE CONVENTIONAL TOBACCO CONTROL POLICY APPROACH – MPOWER

A well-established package of tobacco control measures aims to change the demand for tobacco products by implementing the first three elements of tobacco control discussed in the preceding paragraph.

The WHO and other organisations occasionally use the acronym MPOWER to describe this package.[7] MPOWER has six components:

M onitor tobacco use and prevention policies
P rotect people from tobacco smoke
O ffer help to quit tobacco use
W arn about the dangers of tobacco
E nforce bans on tobacco advertising,
R promotion and sponsorship
aise taxes on tobacco

These measures have contributed to a decline in smoking from very high levels in developed countries in the 1950s-1980s. They also form the basis of the WHO's Framework Convention on Tobacco Control[8], which aims to develop these measures more robustly in developing countries. Although effective, these measures are subject to implementation resource constraints, enforcement burdens and more subtle political limitations.

They include how much the state should intrude in personal choices, whether smoking bans can be justified in private spaces such as homes and raise concern about tobacco taxes being regressive or creating black markets. Each country addresses these issues differently. Harm reduction, the fourth element in the tobacco control strategy outlined above, has received less attention and has evoked hostility from some tobacco control activists.

It has been argued that this is due to confusion about the goals of tobacco policy[9] – whether they are directed at reducing disease, reducing tobacco use, reducing nicotine use or destroying the tobacco industry. This confusion matters because these goals may be in conflict in cases where nicotine products offer much lower disease risk than smoking.

THE TOBACCO HARM REDUCTION APPROACH

When it comes to tobacco harm reduction (THR), the WHO Framework Convention on Tobacco Control (Article 1) (FCTC) explicitly endorses harm reduction strategies in tobacco control[8]:

(d) "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).

This means reducing harm to people who continue to use nicotine or tobacco. Despite this endorsement in the FCTC text, this tobacco harm reduction approach has not yet been expanded in the Convention. It has also not been widely developed as a tobacco control strategy other than by chance.

THE KEY TOBACCO HARM REDUCTION INSIGHT

A crucial insight into tobacco and health strategy is to recognise the ultimate cause of harm. Nicotine is the active drug in tobacco, and the reason why people smoke tobacco.

However, it once again needs to be emphasised that nicotine is not the primary cause of harm arising from smoking. As mentioned before, it has been understood for forty years that[10]:

People smoke for the nicotine but die from the tar.

Nicotine is not a cause of cancer, cardiovascular disease or the respiratory conditions that dominate the ill health from smoking.[11] While pure nicotine is not completely benign, it is widely sold in medicinal form and does not cause any serious illness.[12]

Many decades of experience with Swedish snus (a form of smokeless tobacco), suggests that tobacco and nicotine use can carry a very low risk when there is no combustion.[13]

The US Surgeon General has made a detailed assessment of nicotine risks[14], and though it is possible to measure many effects on the body, these are trivial compared to the harms clearly associated with smoking.

"Tobacco harm reduction relies on technologies that deliver nicotine without smoke – or what are known as 'alternative nicotine delivery systems' (ANDS)."

This insight expands the prospect of "tobacco harm reduction" – a way to use the mildly psychoactive drug nicotine, without the major health consequences of exposure to tobacco smoke.

This relies on technologies that deliver nicotine without smoke – or what are known as "alternative nicotine delivery systems" (ANDS). ANDS are evolving rapidly, partly because advances in battery technology provide high power and energy density in a compact form that works in consumer products. ANDS include vapour products, nicotine inhalers, heated tobacco products, smokeless tobacco products and novel nicotine products delivered through the oral mucosa. There are also more traditional ANDS, such as smokeless tobacco, which can be made at high standards that remove nearly all health risk.

Harm reduction can make a significant contribution to tobacco control. People who smoke regularly visit their health professionals, simply because they are more prone to disease. A significant number of those who smoke can be classified as "inveterate" smokers i.e. those with a long established habit of smoking who are unable or unwilling to quit. Tobacco harm reduction (THR) recognises this problem and offers these smokers a pragmatic alternative.

In essence, therefore, the goal with THR is to minimise harm and decrease total morbidity and mortality, without completely eliminating tobacco and/or nicotine use.

EVIDENCE BASE AND DEFINITIONS OF TOBACCO HARM REDUCTION

In practice, THR refers to substituting the highest risk tobacco products – combustible cigarettes –, with lower-risk nicotine and tobacco products. The latter includes nicotine replacement therapy pharmaceuticals, low-nitrosamine smokeless tobacco products and e-cigarettes (or vaping products). The substitution is entirely aligned with the principles of harm reduction:

- The objective is to reduce harm to health for smokers unable or unwilling to stop;
- The primary intent is not to stop nicotine use altogether, but to prevent harm to the user and those around them; and
- In no way is it intended to minimise or replace evidence-based approaches to prevent smoking initiation, quitting programs and the protection of non-smokers to second hand smoke.

Two groundbreaking publications that provide a solid evidence base for THR have played a key role in helping to raise awareness and better articulate what THR is, and importantly, how health professionals can apply it. They are:

- Clearing the Smoke: Assessing the science base for tobacco harm reduction[16]; and
- Harm reduction in nicotine addiction: Helping people who can't quit.[17]

Health professionals in particular, are well advised to read these reports, since THR incorporates all the policies and methods they employ as professionals and in society to reduce the harm caused by tobacco. This includes harm to the consumers of tobacco and those who are affected as inhalers of second hand smoke.

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HOW OTHER ORGANISATIONS DEFINE THR

The American Association of Public Health Physicians[18] describes tobacco harm reduction in this way:

"Harm reduction is taken to mean encouraging and enabling smokers to reduce their risk of tobacco-related illness and death by switching to less hazardous tobacco products. This switch could be short-term or long-term, partial or full, with the understanding that every time an alternative tobacco product is used in place of a cigarette, risk of tobacco-related illness and death is reduced."

Whereas the harm reduction community has traditionally focused more on drug abuse, harm reduction relating to tobacco has become more prominent in their thinking.

Harm Reduction International's position statement on THR articulates its view on tobacco harm reduction well[4]:

"Tobacco harm reduction is a policy or strategy for tobacco users who cannot or will not stop, which explicitly includes the continued use of tobacco or nicotine and is designed to reduce the health effects of tobacco use. Examples of harm reduction interventions could include using potentially reduced-exposure products (PREPs), reducing consumption, switching to long-term nicotine replacement therapy (NRT), switching to smokeless tobacco products, and using replacement products for temporary abstinence."

Of particular interest is their comparison of a cigarette to a "dirty syringe" [4]:

"The premise behind these strategies is that dependence on nicotine is the critical factor underpinning most tobacco use. However, it is not the nicotine that causes most of the harm but rather some of the other 4000 constituents of cigarette smoke, of which 60 are known carcinogens. Drawing an analogy with illicit drug use, the cigarette is the equivalent of the 'dirty syringe'. Consideration therefore needs to be given to separating the drug from the delivery system. The strategies considered in tobacco harm reduction examine the potential for switching some or all cigarette use to other, less harmful nicotine delivery systems."

For health professionals, this is the essence of tobacco harm reduction. Instead of insisting on absolute abstinence from tobacco and all forms of nicotine, health professionals should assist those who choose to smoke cigarettes, to change to less dangerous forms of nicotine intake.

Experienced practitioners know that this is easier said than done. Patients demand to know what the benefits of such a change will be. They fully deserve a sound, evidence-based response.

THR PRINCIPLES FOR THE BUSY HEALTH PROFESSIONAL

The generally recognised pillars or elements of tobacco harm reduction are:

FUNDAMENTALS FOR THE WISE USE OF NICOTINE

PILLAR 1
DON'T START tobacco use (particularly cigarettes, the most dangerous form)

PILLAR 2
If you have started using tobacco, STOP

PILLAR 3
Protect non-smokers from EXPOSURE to second-hand SMOKE. As mentioned before, a fourth pillar namely, tobacco harm reduction is strongly advocated for individual and public health.

PILLAR 4
If someone finds it impossible to quit, SUBSTITUTE or SWITCH their use of tobacco products from the more dangerous combustible types (e.g. cigarettes), to the less dangerous non-combustible forms of tobacco and nicotine-delivery, (e.g. pharmaceutical nicotine OR smokeless tobacco products such as snus).

Most health professionals have a good understanding of providing advice about products to patients. For this reason, they are in an excellent position to practice THR and help their patients switch to less hazardous forms of tobacco. During this process, health professionals can heed the advice of the Institute of Medicine (IOM)[19]:

"A product is harm-reducing if it lowers total tobacco-related mortality and morbidity even though use of that product may involve continued exposure to tobacco-related toxicants."

WHAT ARE THE KEY BENEFITS OF TOBACCO HARM REDUCTION?

Individual benefits:

Benefits for individuals that smoke are that THR reduces death and disease caused by toxicants in tobacco smoke.

For those who don't smoke, THR prevents second hand smoke and avoids smoking role models, which are a powerful influence on young people.

Societal benefits:

THR can benefit society in several ways:

- Reducing death and disease in both national and global populations;
- Reducing loss of productivity and poverty due to smoking;
- Reducing health costs;
- Reducing the human cost of adverse effects; and
- Reducing fires through careless actions by smokers.

There is overwhelming evidence that smoking cigarettes constitutes the most hazardous form of nicotine-delivery.

Non-combustible forms of tobacco are less harmful than cigarettes, but more hazardous than pure nicotine, which is found in pharmaceutical nicotine products.

In fact, there is a continuum or spectrum of risk related to the different forms of nicotine delivery. For the users of tobacco products, shifting down this continuum reduces the harm they cause to themselves.

At a national level, the Swedish example is most often cited as proof of both harm reduction and its positive societal impact. Sweden has the highest per capita use of the smokeless tobacco product called snus, a smokeless, moist tobacco pouch resembling a small tea bag. Users place the product in the mouth inside the upper lip, between the lip and the gums. Usually "snussers" will keep the product inside their lip for 5-15 minutes to receive the nicotine "kick" they are seeking.[20]

This widespread use of snus, as opposed to cigarette smoking, has been credited as an example of tobacco harm reduction in action. For example, the rates of lung cancer in Swedish men are significantly lower than those in Norway, which has higher rates of cigarette smoking.[6]

Aside from several milestone articles on this specific situation, a substantial body of epidemiological evidence supports these claims. *(Epidemiology is the branch of medicine that deals with the study of the causes, distribution, and control of disease in populations.)*

The popularity and widespread use of snus in Sweden, Norway and Canada over many decades have been the focus of hundreds of public health studies. They have confirmed the harm-reducing impact of snus in individuals and probably in society as well.

Another significant research paper highlights the benefits of tobacco harm reduction. In 2018, Levy et al.[21] used a simulation modelling process to demonstrate the potential deaths averted in the USA by replacing cigarettes with e-cigarettes.

They acknowledge that the tobacco control community has been divided regarding the role of e-cigarettes in tobacco control. However, according to their projections, a strategy of replacing cigarette smoking with vaping would yield substantial life year gains, even under pessimistic assumptions regarding cessation, initiation and relative harm.

Tobacco harm reduction remains controversial[22] [23], but with mounting evidence that it could be transformative in reducing the burden of disease, many scientists now recognise the opportunity to achieve rapid reductions in disease risk.[24]

> "There is mounting evidence that tobacco harm reduction could be transformative in reducing the burden of disease."

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CHAPTER 3

Nicotine – A Misunderstood Molecule

Although nicotine may cause addiction, it does not cause disease. Period.[1] Studies have long established this fact. Therefore, as a harm reduction tool, nicotine is an extremely useful substitute to combustible tobacco. World-renowned researcher in human nicotine pharmacology and a veteran in tobacco control at the Center for Tobacco Control Research and Education at the University of California, Dr Neal Benowitz, states, "Nicotine plays a minor role, if any, in causing smoking-induced diseases."[1][2]

Photo by Ryoji Iwata on Unsplash

Photo by Umit Bulut on Unsplash

Tragically, significant myths about nicotine still persist among physicians and the public alike.[1] The misperception of nicotine's harms among health-care professionals is unacceptable and not in the best interest of their patients.

Patel et al.'s[1] [3] 2013 survey at the University of Louisville, KY consisted of 826 full time faculty members in the schools of medicine, public health, dentistry and nursing (57% male respondents). Of the participants, 38% believed that even separate from smoking, nicotine is a high-risk factor for heart attack and stroke. Furthermore, 50% regarded nicotine itself as a moderate risk factor.

For cancers, 38% of the faculty deemed nicotine a high-risk factor and 37% a moderate risk factor. These percentages were 32% and 40% respectively for oral cancer. The male professor respondents appeared moderately better informed than their female counterparts, as male professors were more likely to rate cigarettes as riskier than nicotine (by odds ratios of 1.88 to 2.30).[1] [3]

In 2019, Ferrara et al.[1] [4] *completed an online survey of 256 European Union residents in public health (143 female/ 106 male). Of the respondents, 62% held that nicotine itself causes cancer and more than 72% believed that atherosclerosis is caused by nicotine.*

If health professionals don't understand nicotine, how can we expect the public to know that nicotine does not cause disease? Consider, for example, that in the UK, 40% of the public believe that nicotine causes smoking-related cancers.[1] [5]

Male and female smokers equally hold a widespread misperception that nicotine causes disease. This could, explain in part, the comparatively low utilisation of Nicotine Replacement Therapy (NRT).[1] [6]

A 2016 study of 1 047 clients at the UK stop-smoking services found that even among smokers who chose NRT for treatment, as low as 6.0% (CI 4.3, 8.3) were using NRT at the one-year follow-up, which indicates the limited success of NRT for substitution.[1] [7]

According to Abrams et al.[1] [8]*, it is critical to separate the consequences of nicotine addiction from concerns regarding the harm caused to smoking adults: "The mistaken public beliefs that nicotine is the cause of disease risk and cancer, rather than the smoke from combustion, must be dispelled."*

Without question, there is an urgent need for health professionals and the public to have access to accurate information about the risk profile and evidence-base for therapeutic and recreational nicotine.[1]

The patients who value nicotine are not only those who are trying to quit smoking with the help of nicotine replacement therapy. It is also those who find nicotine useful to improve productivity, enhance focus and reduce anxiety. Another patient group that uses smoking as a way to cope better suffer from certain mental health conditions such as depression, attention deficit disorders and schizophrenia. Presumably, the nicotine intake delivers part of the benefits they experience.

Patients with schizophrenia have a high rate of cigarette smoking. They exhibit profound deficits in sensory processing, which the acute actions of smoke-inhaled nicotine can improve. In a recent study, Dulude et al.[9] showed that acute nicotine can normalise some aspects of sensory memory processing in patients with schizophrenia. This might have implications for understanding the close relationship between tobacco smoking and schizophrenia. In addition, it may reinforce the need to develop nicotinic pharmacotherapies to alleviate sensory memory impairments in schizophrenia.

Still the biggest public health problem is that almost one fifth of all people consume nicotine by smoking cigarettes. Although the hazards of smoking are well documented, smokers still choose to continue the habit, notwithstanding high taxes, restrictions of use, broad social disapproval and the knowledge that they do harm to their own and others' health.

WHY IS IT CALLED NICOTINE?

Nicotine derives its name from Jean Nicot de Villemain, a French diplomat and scholar, who served as the French Ambassador in Portugal from 1559 to 1561. He had a fascination for the use of tobacco snuff by the Portuguese locals. He sent tobacco leaves and seeds, which originally came from Brazil, to Paris because of the interest in their medicinal use.

He described the effects of the tobacco plant as a "Panacea" – a term derived from the Greek goddess of healing. It was thought to be a remedy for all diseases. The snuff made from the tobacco plant became quite fashionable in Paris, especially among the rich. In time, the tobacco plant became known as Nicotiana tabacum[10], while the active ingredient was named nicotine.[11]

> **"Nicotine derives its name from Jean Nicot de Villemain, a French diplomat and scholar, who served as the French Ambassador in Portugal from 1559 to 1561."**

ORIGINS AND BIOCHEMICAL STRUCTURE OF NICOTINE

Surprisingly, nicotine is found in several plants including tomatoes, aubergines and even potatoes. However, the largest quantities are found in the tobacco plant. It is interesting to note that, despite centuries of tobacco use, scientists were only able to identify the active ingredient of the tobacco plant in the laboratory during the early 1800s.

Two researchers, Cerioli and Vauquelin, successfully extracted an oily substance from the plant, first naming it "nicotanine" after Jean Nicot. Later, in 1828, Posselt and Reimann, two researchers from the University of Heidelberg, purified the extract and called it "Nikotin". In its pure form, nicotine is a colourless or pale-yellow oily liquid. The chemical formula for nicotine, $C_{10}H_{14}N_2$, was established by 1840 and since then, it has been possible to synthesise the compound in a laboratory. Tobacco products contain hundreds of substances, while the smoke produced when setting it alight contains more than 6 000 substances or toxicants. However, the one common factor found in all types of tobacco products is nicotine, whether as the smoked or the smokeless forms.[12] [13]

HOW THE BODY ABSORBS NICOTINE

For the health professional, it's important to know the basic mechanism of nicotine absorption and distribution in the body. Nicotine is broken down in the liver by the P450 enzyme system, which is also active in metabolising many other substances.

This must be taken into account when prescribing medicinal nicotine for patients. The main metabolised product of nicotine is cotinine, which is excreted by the kidney. The kidneys excrete about 10% of nicotine unchanged, which is a key factor to remember in patients with impaired renal function. Nicotine is also secreted in the saliva and breast milk and crosses the placenta.

> **"It is estimated that nicotine from smoked tobacco reaches the brain about 10 seconds faster than from an intravenously administered drug."**

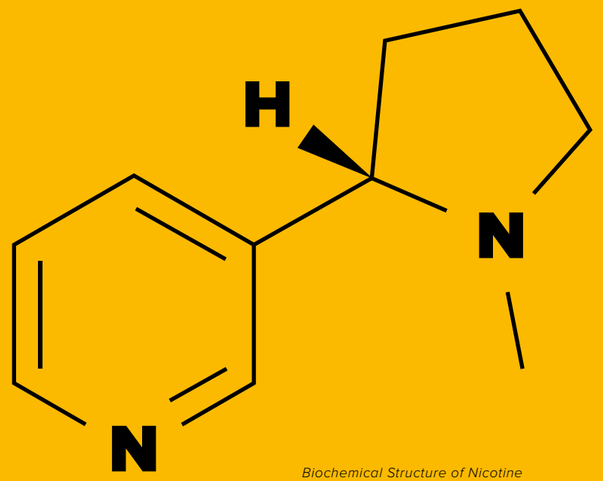
The main effect of nicotine in the body is due to the direct stimulation of nicotinic acetylcholine receptors that are present in the adrenal medulla, central nervous system and skeletal muscle.

The initial stimulating effect of nicotine occurs when stimulation of the adrenal gland leads to the release of adrenalin. Adrenalin increases blood glucose and respiration and causes vasoconstriction (narrowing of the arteries), which leads to higher blood pressure and increased heart rate. In the heart, it has the potential to cause arrhythmias (irregular heartbeat), while arterial constriction can lead to angina. In the brain, this stimulation (especially via the dopamine reward circuit) leads to feelings of relaxation and euphoria. It also causes sharpness and alertness.

Because of the overall positive effect of nicotine in the brain – especially concerning sharpness, alertness and concentration – it can be rather hazardous to force some patients that perform high performance jobs such as pilots, surgeons and heavy machinery operators to quit cold turkey. The loss in concentration and alertness combined with withdrawal symptoms can be quite dangerous.[14]

As nicotine undergoes extensive metabolism in the body, the breakdown of nicotine into six metabolites (mainly in the liver), enables scientists to measure the success of tobacco cessation objectively. Cotinine has the largest concentration of nicotine metabolites in blood and is often used to verify whether a patient has truly stopped smoking.

It also has a longer plasma half-life than nicotine (16-20 hours), so it useful to request this laboratory test when appropriate.[15]



Biochemical Structure of Nicotine

NICOTINE AS THE MAJOR ADDICTIVE SUBSTANCE IN TOBACCO

Nicotine provides its consumers with a "hit" or "rush" that is most pronounced in cigarette smoking. This is one reason why nicotine is so addictive when delivered by cigarettes. However, other factors also contribute to the addictive properties of nicotine.

As Dr Neal Benowitz[2] points out, "Tobacco addiction (like all drug addictions) involves the interplay of pharmacology, learned or conditioned factors, genetics, and social and environmental factors (including tobacco product design and marketing)."

Some health professionals may wonder why it is so difficult to use medicinal nicotine to wean their patients off cigarettes, the answer lies in how the body absorbs, distributes and breaks down nicotine. While nicotine uptake via pharmaceutical nicotine products like gum might take minutes before absorption, arterial levels of nicotine take a mere 20 seconds to peak after each puff of a cigarette. Incredibly, it is estimated that nicotine from smoked tobacco reaches the brain about 10 seconds faster than from an intravenously administered drug.[16]

This effect is further enhanced by the fact that smoking, according to Benowitz [2], is actually "a highly efficient form of drug administration", since the rapid rates at which inhaled nicotine is absorbed and enters into the brain reinforce the effects of the drug.

Even compared to hard-line drugs such as cocaine and morphine, nicotine is five to ten times more potent in terms of its ability to produce behavioural and psychic effects associated with addiction potential in humans, including measures of pleasure and satisfaction.[16]

In contrast, the various forms of medicinal nicotine (NRTs or nicotine replacement therapy) deliver nicotine much slower.[17] NRTs were specifically designed to minimise their addiction potential.

RISKS OF MEDICINAL NICOTINE

The use of nicotine replacement therapy over the last 20 years or more has offered the best evidence in clinical trial and observational study settings that nicotine is a safe drug.[18][19]

While NRTs may have some local adverse effects, these are rather linked to the form of nicotine intake. For example, first-time users of the Swedish "Snus" pouches are likely to report a burning, uncomfortable sensation and local irritation of the mouth.

While there is no clear evidence that nicotine can induce acute cardiovascular effects, it has been associated with minor cardiovascular adverse effects such as palpitations.[20][21]

The long-term use of medicinal nicotine might include some risks[22]:

- The direct effect on blood vessels might cause endothelial dysfunction; however, various studies have shown no increased risk of cardiovascular disease among people who continue to smoke while using medicinal nicotine, or in cardiovascular patients who use medicinal nicotine;
- Impaired wound healing; and
- Potential neurotoxicity in the developing foetus.

DOES MEDICINAL NICOTINE CAUSE CANCER?

Physicians can expect patients to ask whether medicinal nicotine causes cancer. This is an ongoing debate and there is conflicting evidence that nicotine might promote the growth of cancerous tumours in humans.[23][24]

Some smokers who switch to smokeless tobacco may have an increased risk of lung cancer compared to smokers who quit tobacco use altogether. However, exposure to tobacco-specific nitrosamines (TSNAs) from smokeless tobacco as opposed to nicotine, could account for, or contribute to the increase in lung cancer risk. The Swedish experience is another fact that mitigates against nicotine being carcinogenic. Lifelong use of snus among Swedish men does not increase risk of any cancer except pancreatic cancer.[25]

> **"Compared to the risk that smokers face from cigarettes, health professionals can rest assured that their patients could use nicotine products such as nicotine replacement therapy safely."**

Even more persuasive is the groundbreaking 2007 report of the Royal College of Physicians, *"Harm Reduction in Nicotine Addiction: Helping people who can't quit"*.

They conclude[26]: *"There is no direct evidence that NRT therapy is carcinogenic or influences the risk of other common smoking-related diseases in humans."* Compared to the risk that smokers face from cigarettes, health professionals can rest assured that their patients could use nicotine products such as NRT safely.

NICOTINE EXPERTISE OF TOBACCO AND NICOTINE COMPANIES

An important fact about nicotine, which the public health community often overlooks, is that tobacco and nicotine companies have a deep understanding of nicotine. Indeed, they have long used it for their commercial benefit. Lead nicotine researcher at Philip Morris Tobacco Company, William L Dunn, summed up the effect of nicotine in this way[27][28]:

"The cigarette should be conceived not as a product but as a package. The product is nicotine... Think of the cigarette pack as a storage container for a day's supply of nicotine... Think of the cigarette as a dispenser of a dose unit of nicotine... Think of a puff of smoke as the vehicle of nicotine... Smoke is beyond question the most optimized vehicle of nicotine and the cigarette the most optimized dispenser of smoke."

As a rule, scientific data developed by the tobacco industry is not regarded as credible. However, their nicotine expertise and scientific data could be part of finding solutions to reduce the harm caused by smoked tobacco.

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CHAPTER 4

Products used in Tobacco Harm Reduction

Mass consumption of tobacco and nicotine products has had an interesting, cyclical pattern since the 17th century. The pipe was the tobacco product of choice in Europe during the 17th century, but snuff overtook it at the turn of the 18th century. Cigars then took the lead by the end of the 18th century. Next, hand-rolled cigarettes followed when leftover cigar paper was used to roll cigarettes.

Everything changed with the introduction of the Bonsack machine in the early 1880s. This 'disruptive innovation' cigarette-rolling machine changed the tobacco industry forever. It quickly replaced hand rolling and the mass-produced cigarette became the fashionable tobacco product of the time. Cigarettes, and in particular white cigarettes, became the global giant product in the tobacco industry.[2]

Photo by Joshua Earle on Unsplash

Photo by cottonbro from Pexels

COMBUSTIBLE TOBACCO: KNOW THE PRODUCT TO UNDERSTAND THE PROBLEM

Before analysing products that are potentially less harmful than traditional tobacco, it is useful to revisit cigarettes, one of the most commercially successful, but sadly also one of the deadliest products of all time.

- Distribution: Cigarettes are the most widely consumed tobacco product and nicotine-delivery vehicle. Of all the tobacco products sold, 92% are cigarettes (approximately 6.3 trillion cigarettes are consumed per year). Although most cigarettes are manufactured commercially, some are hand-rolled. Over 15 billion cigarettes are smoked worldwide every day. One in three cigarettes smoked in the world today is smoked in China.

- Mode of action: Cigarettes are set alight and the smoke inhaled into the lungs, where it is very rapidly absorbed into the bloodstream. Physiologically, this means that nicotine enters the arterial blood supply and reaches the brain within seconds. A cigarette delivers a potent 'hit' or 'rush' for the smoker – much more effectively and faster than any other nicotine-delivery device –, which greatly enhances its addictive potential.[3] [4] Each cigarette has on average 10-12 mg of nicotine content.

> **"A cigarette delivers a potent *hit* or *rush* for the smoker – much more effectively and faster than any other nicotine-delivery device – which greatly enhances its addictive potential."**

- Risk profile: Cigarettes are the most hazardous nicotine-delivery vehicle on the market, causing harm to almost every part of the body. Cigarettes are responsible for 90% of all cancers, 30% of all heart disease and 30% of all chronic obstructive lung disease.[5]

NON-COMBUSTIBLE, NICOTINE-BASED PRODUCTS: THE SOLUTION THROUGH DISRUPTIVE INNOVATION

In health care, the ground-breaking discovery of antibiotics had a profound effect on public health, with many hundreds of millions of lives saved thanks to a drug that could successfully combat bacterial disease. Similarly, statins have played a significant role in the prevention of high cholesterol and cardiovascular disease. Yet, drivers of positive change need not always be new inventions. If we can modify existing products to improve health, or at least reduce harm, they can also transform society in a positive way.

> **"We are standing on the cusp of a quickening of especially nicotine product disrupters. Consumers are demanding new, less harmful, user-friendly, effective and fast acting nicotine products, which can be used as substitutes for cigarettes."** *– Dr Delon Human, CEO, Africa Harm Reduction Alliance (AHRA)*

In this changing landscape, it is important for health professionals to have at least basic knowledge of the tobacco and nicotine products currently available. It is even more important that they understand the relative risks involved in the use of these different products. It needs to be stressed that there is a very large difference in risk profile between the various product categories and even inside the categories.

"The epidemiology tells us that tobacco products delivering nicotine vary considerably in harmfulness. Within each product category there is a (sometimes wide) variation of dose and manner of use, but the extreme ends of the spectrum differ in harmfulness by orders of magnitude."[1][6]

ALTERNATIVE NICOTINE DELIVERY SYSTEMS (ANDS)

A growing range of technologies can provide an acceptable or satisfying dose of nicotine without combustion. These alternative nicotine delivery systems (ANDS) are evolving rapidly, partly due to advances in battery technology, which provide high power and energy density in a compact form that works in consumer products. There are also more traditional ANDS such as smokeless tobacco, which remove nearly all health risk and can be made at high standards.

Please note the diagram below illustrates 2020 products and is not intended to be a comprehensive review of all the products available.

Vapour Products

Crossover NRT

Heated Tobacco Products

Smokeless Tobacco

Inhalers

Novel Nicotine Products

Alternative Nicotine Delivery Systems

Vapour products use a battery to heat liquid containing pharmaceutical grade nicotine, an inert diluent (such as propylene glycol) and flavourings. This creates an aerosol of tiny droplets of nicotine-containing liquid, which the user then inhales, and nicotine is absorbed in the mouth, throat and lungs. There are many different forms of these products:

- 1st generation devices resemble cigarettes and are often disposable;
- 2nd generation devices look more like large pens; they are both reusable and refillable with liquids or liquid-containing cartridges;
- 3rd generation devices are modular and are available in a wider variety of shapes, sizes and power outputs. Users can buy batteries, heating coils, liquids and other components separately and assemble their own system.
- The latest generation of e-cigarettes are pod mod devices, similar to pens, with liquids supplied in pod-like cartridges,
- Other vapour devices include e-shisha, e-hookah, e-pipes and e-cigars.
- These carry nicotine and mimic the tobacco equivalent, but instead of tobacco, use electricity for heat and a clean liquid.

Inhalers and NRT inhalers use gas pressure to create an aerosol, which the user then inhales without any heating process.

Heated tobacco products use a battery or other heating source to heat tobacco and create a vapour that takes up nicotine and flavours from the tobacco. These products aim to mimic the experience of smoking closely, but with much lower risk.

Smokeless tobacco products are sucked or chewed instead of smoked. These products have existed for many years and some, like the toombak used in Sudan, are traditional. Risks from smokeless tobacco arise from impurities or hazardous agents in the tobacco itself; however, these can be controlled in the curing and pasteurising process.

Novel nicotine products can deliver nicotine in various forms, including gum, lozenges, Transdermal patches, films, liquids and pouches. Some products may be sold as pharmaceuticals, while others may be positioned as OTC consumer products.

Altogether, these emerging and established products add up to a major disruption of the US$800 billion global market for cigarettes. There is not only a powerful public health rationale to disrupt the global cigarette trade but also a potent business rationale.

It is useful to re-assess the current scientific literature on the main categories of tobacco and nicotine products. These are widely used as 'potentially reduced risk' products, as summarised in the excellent narrative review "Tobacco Harm Reduction in the 21st Century" by O'Leary and Polosa.[1]

SNUS AND SMOKELESS (ORAL) TOBACCO

Snus has been used in Sweden and other Scandinavian countries for more than 200 years. Resembling a small teabag, snus itself is an oral tobacco product that contains processed, normally pasteurised tobacco in a paper pouch. The user places the pouch in the mouth between the gum and cheek. Note that snus is not the same as loose snuff, chewing or dip tobacco.

Because of the pasteurisation, snus contains a greatly reduced level of nitrosamines and tobacco compounds that cause tobacco-related diseases.[1][7] Another harm reduction benefit of snus is that its use does not generate second-hand smoke exposures. We can also observe the harm reduction potential of snus at a population level.

In a comparative case study, Ramström and Wikmans[8] compared rates for smoking-related mortality between male snus users in Sweden to men in European countries overall where snus is banned.

Analysing 2004 data from the WHO Global Report on Mortality Attributable to Tobacco, they found that both populations had a similar prevalence of daily tobacco use. However, Swedish men aged between 60-69 years not only had lower rates of lung cancer deaths (87 per 100 000) than the European Union average (220 per 100 000), but also lower rates of cardiovascular death (72 vs 170 per 100 000). [1][8]

Although the prevalence of regular female snus users is far lower than for male users in Sweden (4% compared to 19% in 2015), it is interesting that snus uptake by smokers of either gender resulted in high smoking quit rates of 71.6% for women and 76.3% for men.[1][9]

In addition, regular snus use by youth appears to be protective against smoking uptake.

This is even more prevalent among female youth – only 8.2% of girls and 17.6% of boys who regularly used snus progressing to daily smoking.[1][9]

At an individual level, Meier et al.'s[10] eight-week multi-site trial was a randomised controlled study of 150 adult smokers (85 male, 65 female). They compared usual cigarette use, partial substitution of snus for cigarette use and complete substitution of snus.[1][10]

They concluded that complete substitution of snus reduced exposure to the harmful constituents of acrolein, crotonaldehyde, acrylonitrile and acrylamide, but not others (nitrosamine ketone [NNK], propylene oxide, phenanthrene).[1][10] Additionally, snus-only users had significantly lower levels of carbon monoxide (eCO) – a cardiovascular risk factor – than the smoking arm.

On 22 October 2019, the United States Food and Drug Administration (USFDA) validated the harm reduction value of snus by granting Swedish Match USA a 'modified risk order' for eight general brand snus products.[1][11]

The USFDA has established a category for proven reduced-risk products. In this category, Swedish Match snus is the first set of modified risk tobacco products (MRTP) to receive USFDA approval.[1][11] In this regard, the USFDA announced, "the available scientific evidence, including long-term epidemiological studies, shows that relative to cigarette smoking, exclusive use of these specific smokeless tobacco products poses a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema and chronic bronchitis".[11]
The USFDA further noted that smokeless products sold in the US had much higher levels of two major carcinogens – N-Nitrosonornicotine (NNN) and nitrosamine ketone (NNK).[1][11]

Acquiring MRTP designation for products from the USFDA is a lengthy and stringent process, which can be terminated at any point.[1] First is a pre-meeting with the tobacco products scientific advisory committee, then a filing review, a substantive review with a comment period, and, lastly, final action.[1][12] Even after approval, post-market reporting and renewal must be completed.

The filing must be submitted for each individual product. All company testing reports, studies on population and individual health effects, proposed product packaging, labelling and advertising must be included.[1][12] In addition, it needs to include product testing, which demonstrates how customers actually use the product and assess their understanding of its risks.[1][12]

Aside from snus, other smokeless tobacco products show evidence of harm reduction. A 2019 study of over 46 000 men in the age range 40-79 years – 1987 to 2010 (US National Health Interview Survey) – showed no increases in mortality among smokeless-tobacco-users, as compared to never-tobacco-users for cardiovascular diseases, all cancers and malignancies.[1][13]

As oral tobacco products (differing from country to country) involve significantly different levels of risk for oral cancers[14], they vary in efficiency for tobacco harm reduction.[1][14]

An astounding example of this substantial difference in risk is the Ryman et al.[15] study, involving 879 Yup'ik people of Alaska (406 male, 468 female). It looked at the use of Iq'mik (a smokeless tobacco made with tree ash). As indicated by multiple biomarker tests, this five-year study found that users of Iq'mik have a lower risk for negative cardiometabolic health than non-smokers.[1][15].

HEATED TOBACCO PRODUCTS

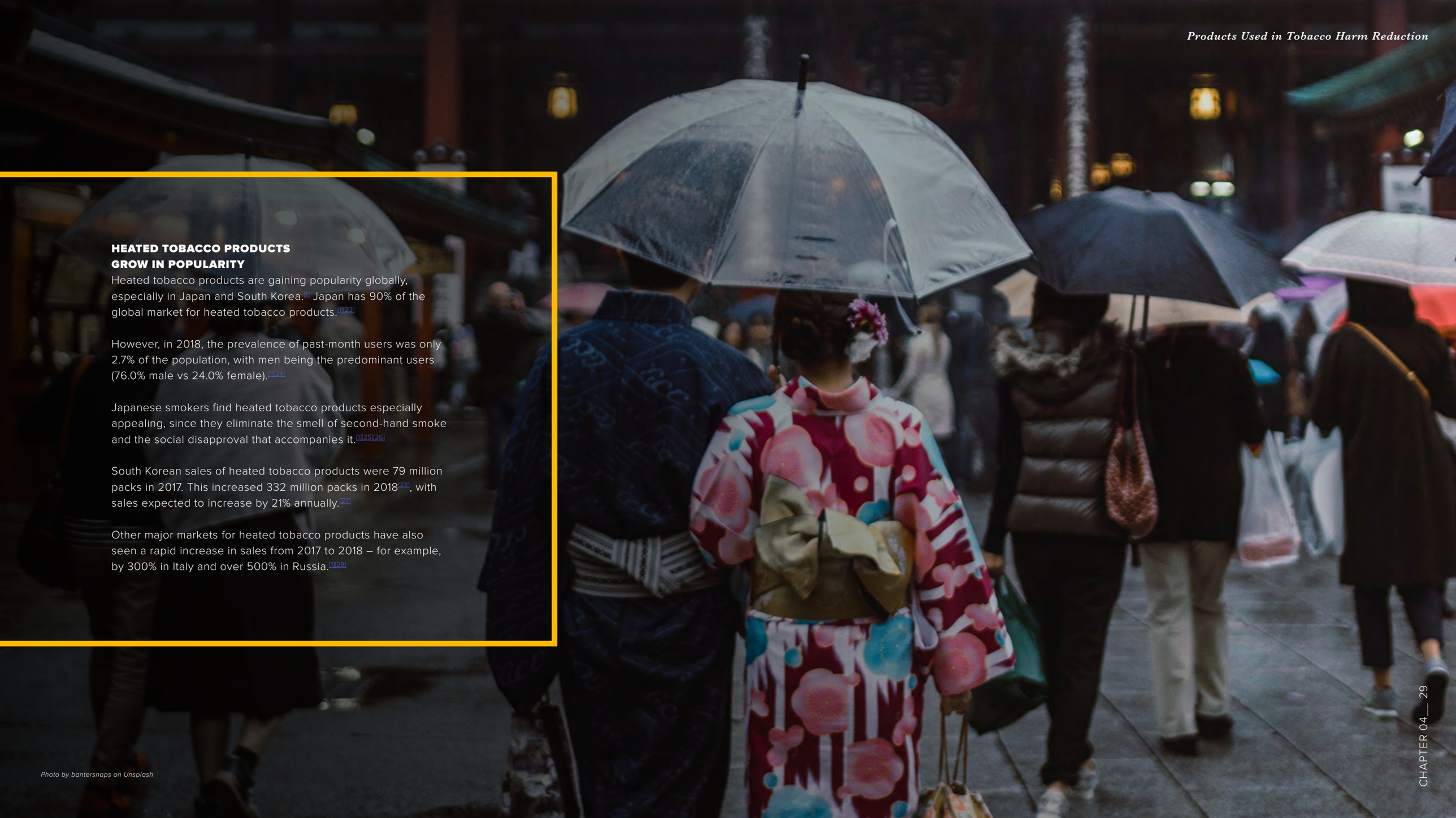
Heated tobacco products (also known as heat-not-burn), use an electronically controlled holder to apply heat to tobacco sticks, plugs or capsules. The user places the tobacco product in a holder and draws on it in the same fashion as cigarettes or cigars.

Some examples of heat-not-burn products are 'IQOS' (Philip Morris International), 'glo' (British American Tobacco) and 'Ploom TECH' (Japan Tobacco International).

There is limited evidence that while heated tobacco products offer the potential for tobacco harm reduction, they do not provide as much reduction in toxicants as e-cigarettes.[1][18]

Some studies that illustrate reductions in exposures of heated tobacco products compared to cigarettes are[1]:

- In a human subject clinical trial, 12 adult smokers (6 male, 6 female) experienced no elevation in eCO levels (a risk factor for cardiovascular disease) after brief use of a heated tobacco product[19];
- A trial (20 male, 10 female) found a small but minimal increase in eCO levels[20];
- A toxicological product assessment conducted with the Canadian machine smoking procedure found levels of aldehydes at approximately 80-95% lower than cigarettes and volatile organic compounds approximately 97-99% lower[21]; and
- Another toxicological study using a margin of exposure analysis reported that a heated tobacco product reduced the risks from exposure to nine out of the 20 most toxic compounds in tobacco.[22]



HEATED TOBACCO PRODUCTS GROW IN POPULARITY

Heated tobacco products are gaining popularity globally, especially in Japan and South Korea.[1] Japan has 90% of the global market for heated tobacco products.[1][23]

However, in 2018, the prevalence of past-month users was only 2.7% of the population, with men being the predominant users (76.0% male vs 24.0% female).[1][24]

Japanese smokers find heated tobacco products especially appealing, since they eliminate the smell of second-hand smoke and the social disapproval that accompanies it.[1][25][26]

South Korean sales of heated tobacco products were 79 million packs in 2017. This increased 332 million packs in 2018[23], with sales expected to increase by 21% annually.[27]

Other major markets for heated tobacco products have also seen a rapid increase in sales from 2017 to 2018 – for example, by 300% in Italy and over 500% in Russia.[1][28]

Photo by bantersnaps on Unsplash

E-CIGARETTES (ELECTRONIC NICOTINE DELIVERY SYSTEMS OR 'ENDS')

Electronic cigarette products operate by heating an element that vaporises an e-liquid solution mainly consisting of glycerol, propylene glycol, distilled water and flavourings (which may or may not contain nicotine).

The heating process generates an aerosol (vapour) that the user inhales, also referred to as vaping. The design and efficiency in nicotine delivery of e-cigarettes have improved substantially since they were introduced into the market in 2006.[1]

There are currently three e-cigarette designs/generations[1]:

- A disposable product;
- A reusable, refillable device filled that users fill with liquid from a tank system; and
- A reusable device, which attaches to pre-filled cartridges ('carts' or 'pods') such as JUUL.

The current design of many e-cigarette devices enables the user to regulate its power and affect the heating temperature.[1] The worldwide popularity of e-cigarettes have also grown substantially from about seven million users in 2011, to 41 million in 2018.[1][29]

The European Union regulates e-cigarettes through its Tobacco Products Directive 2014/40/EU, while in the US they are regulated under the Deeming Rule (published 5 May 2016).[1][30]

Outside of the US and the EU, no other countries that permit the sale of e-cigarettes have enacted any product safety requirements beyond regulating nicotine content.[1][30] New studies provide promising evidence for the harm reduction potential of e-cigarettes.[1]

In 2019, a randomised controlled trial[31] of 886 motivated quitters (460 male, 424 female) at the UK National Heath Stop Smoking Service compared e-cigarettes and NRTs for successful smoking cessation at one year.

Using biochemical verification, the trial defined successful cessation as no more than five cigarettes after the 2nd week and calculated dropouts as treatment failures (intention-to-treat analysis).[1][31]

The quit rate for e-cigarettes was 18.0% compared to a 9.9% quit rate with Nicotine Replacement Therapy NRT. (Relative Risk (RR) 1.83; Confidence Intervals (CI) 1.30, 2.58; $p < 0.001$; 85% power).[1][31]

At the one-year follow-up, 80% of the participants (63 of 79) who achieved one-year abstinence with e-cigarettes were still using them.[1][31] This is a possible indication of the effectiveness of e-cigarettes for preventing relapse.[1]

The cross-sectional trial by Shahab et al[32] of 181 participants (110 male, 71 female) used biochemical testing for biomarkers of exposure in five groups of 36–37 participants.

These were cigarette-only-users, e-cigarette-only-users (>6 months smoking cessation), NRT-only-users (>6 months smoking cessation), dual-users of cigarettes and e-cigarettes and dual-users of cigarettes and NRT.[1][32]

The e-cigarette-only users had significantly lower NNAL levels than all other groups – equivalent to a 97% reduction compared to combustible cigarette-only users.[1][32]

A particularly important finding is the lowered biomarker of 1, 3–butadiene (BDE) for e-cigarette-only-users: 11.0% (CI 7.5, 16.1) that of smokers[1][32], since BDE is the greatest source of cancer risk in cigarettes.[1][33]

Additionally, the acrylonitrile levels of e-cigarette-only-users recorded at only 2.9% (CI 1.7, 4.7) that of smokers[1][32] – an extremely positive outcome as acrylonitrile is the second-highest source of cancer risk for smokers.[1][33]

While biomarkers don't indicate disease rates, substantially reducing e-cigarette-only-users' exposures is a positive marker for tobacco harm reduction. The use of e-cigarettes (compared to smoking) also eliminates elevated levels of exhaled carbon monoxide, a major risk factor for cardiovascular disease as demonstrated in a clinical trial of 30 participants (20 male, 10 female).[1][20]

Although biomarkers don't indicate disease rates, substantially reducing e-cigarette-only-users' exposures is a positive marker for tobacco harm reduction. The use of e-cigarettes (compared to smoking) also eliminates elevated levels of exhaled carbon monoxide, which is a major risk factor for cardiovascular disease as demonstrated in a clinical trial of 30 participants (20 male, 10 female).[1][20]

As discussed, when it comes to stopping smoking, relapse is a common problem.[1] Giovenco and Delveno's[34] 2018 study indicates the effectiveness of e-cigarette use to prevent relapse. They based their study on combined data from the 2014 and 2015 US National Health Interview Surveys (53.6% male).

They found that daily e-cigarette users had a higher prevalence of having quit during the prior six years than smokers who had never used e-cigarettes: 52.2% vs 28.2%, APR: 3.15 [2.66, 3.73].

After adjustment for covariates, daily e-cigarette use was consistently the strongest independent correlate of smoking cessation and did not vary by gender.[1][34] "After adjustment for covariates, daily e-cigarette use was consistently the strongest independent correlate of smoking cessation and did not vary by gender."[1]

The question thus is: "How could the use of e-cigarette use prevent relapse? A qualitative study of 40 UK vapers (20 male, 20 female) suggests a possible solution – "for some, using e-cigarettes can substitute 'the physical, psychological, social, cultural and identity-related dimensions that were previously enjoyed about tobacco smoking".[35]

E-cigarette use is therefore uniquely suitable to support long-term smoking relapse prevention. Furthermore, e-cigarette substitution for smoking could also be supported by these factors.[1][35]

NICOTINE REPLACEMENT THERAPY (NRT) OR MEDICINAL NICOTINE

Health professionals are most familiar with this form of nicotine, also called medicinal nicotine. NRT is available in different formats:

TYPE OF PRODUCT	NICOTINE DELIVERY
Gum, *available in doses of 2 & 4 mg*	Actual systemic dose is 1 mg from the 2 mg gum and 2 mg from the 4 mg gum.[36]
Transdermal patches	Dose is normally 15 mg for 16 hours, or 21 mg for 24 hours.[37]
Nasal spray	This form of medication is absorbed into the systemic circulation faster than any other NRT. It delivers 0.5 mg nicotine per 0.5 ml spray.
Nicotine inhaler	Each cartridge contains 10 mg nicotine. The average systemic dose delivers 2 mg.[38]
Nicotine lozenges	2-4 mg nicotine. Absorption is similar to that of nicotine gum.[39]

Nicotine replacement therapy has been demonstrated to be a key element of tobacco cessation and can be used in almost all cases, other than where use of nicotine medication is contra-indicated.[40][41]

It is not surprising; therefore, that Ministries of Health and the World Health Organization have encouraged physicians and health professionals worldwide to offer medical help for those patients who want to quit smoking.

> "At present, there is no clear evidence from clinical trials or observational studies that NRTs cause any of the major health problems associated with cigarette smoking, including lung cancer."

RISK PROFILE OF NRTs

As with any drug, long-term use of NRTs might offer more insight into other potential side effects, which health professionals will then need to take into consideration when helping their patients quit smoking.

Extensive research conducted on NRTs – in both the pre-marketing phase and in post-marketing surveillance – indicates the following recognised side effects of these products[42]:

- ***Cardiovascular effects*** – No increased risk of cardiovascular disease has been found in cardiovascular patients who use NRTs. Nicotine does, however, have a direct effect on blood vessels and this can also impair wound healing[43];
- ***Toxicity to a developing foetus*** – There may be a link between NRT use and complications of pregnancy and sudden infant death syndrome. However, the risk is still much lower than the risk of continued smoking[44];
- ***Nicotine and cancer*** – This myth-ridden area is where we should actively encourage health professionals to focus on solid science and play a decisive role in the rehabilitation of nicotine. It is inconceivable that the collective nicotine blind spot has persisted for so long. Instead of tackling the question "Does nicotine cause cancer or not?" we have allowed myths to continue and even shape perceptions of nicotine and accepted 'wisdom'.

At present, there is no clear evidence from clinical trials or observational studies that NRTs cause any of the major health problems associated with cigarette smoking, including lung cancer[45].

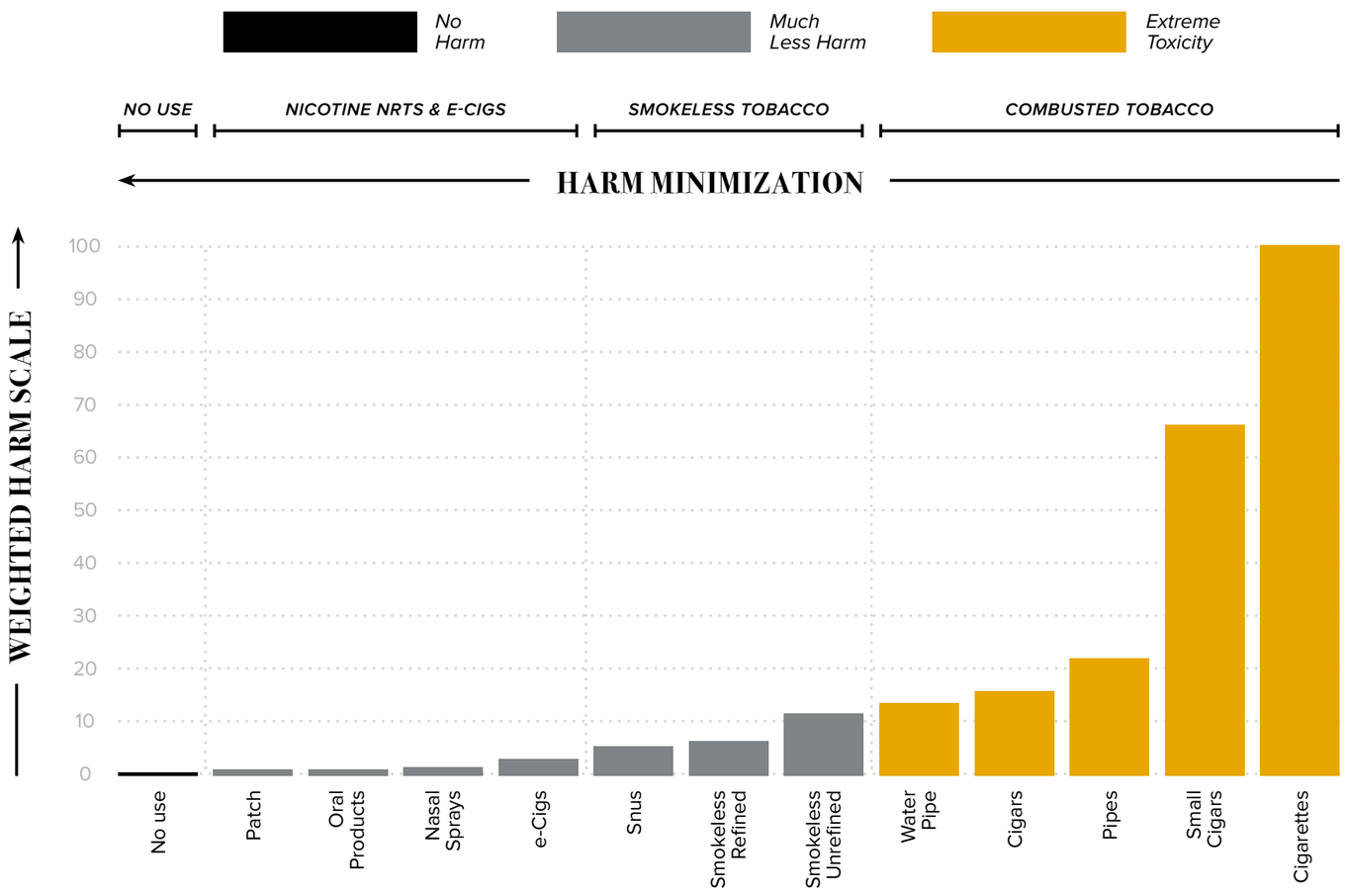


Figure 1: Products along the harm minimization continuum.[46][47]

RISK CONTINUUM

To place the aforementioned products into the context of its relative harm, the harm continuum (Figure 1) was developed, first by Nutt et al.[47], and modified with permission by Abrams et al.[46]

The harm continuum powerfully illustrates the point, that none of these products are completely safe. Rather, that E-cigarettes are significantly less harmful than combustible cigarettes. The NRTs are safe enough that most medicine regulatory bodies have approved its use for as an acceptable strategy to quit smoking, thereby reducing morbidity and mortality from smoking.

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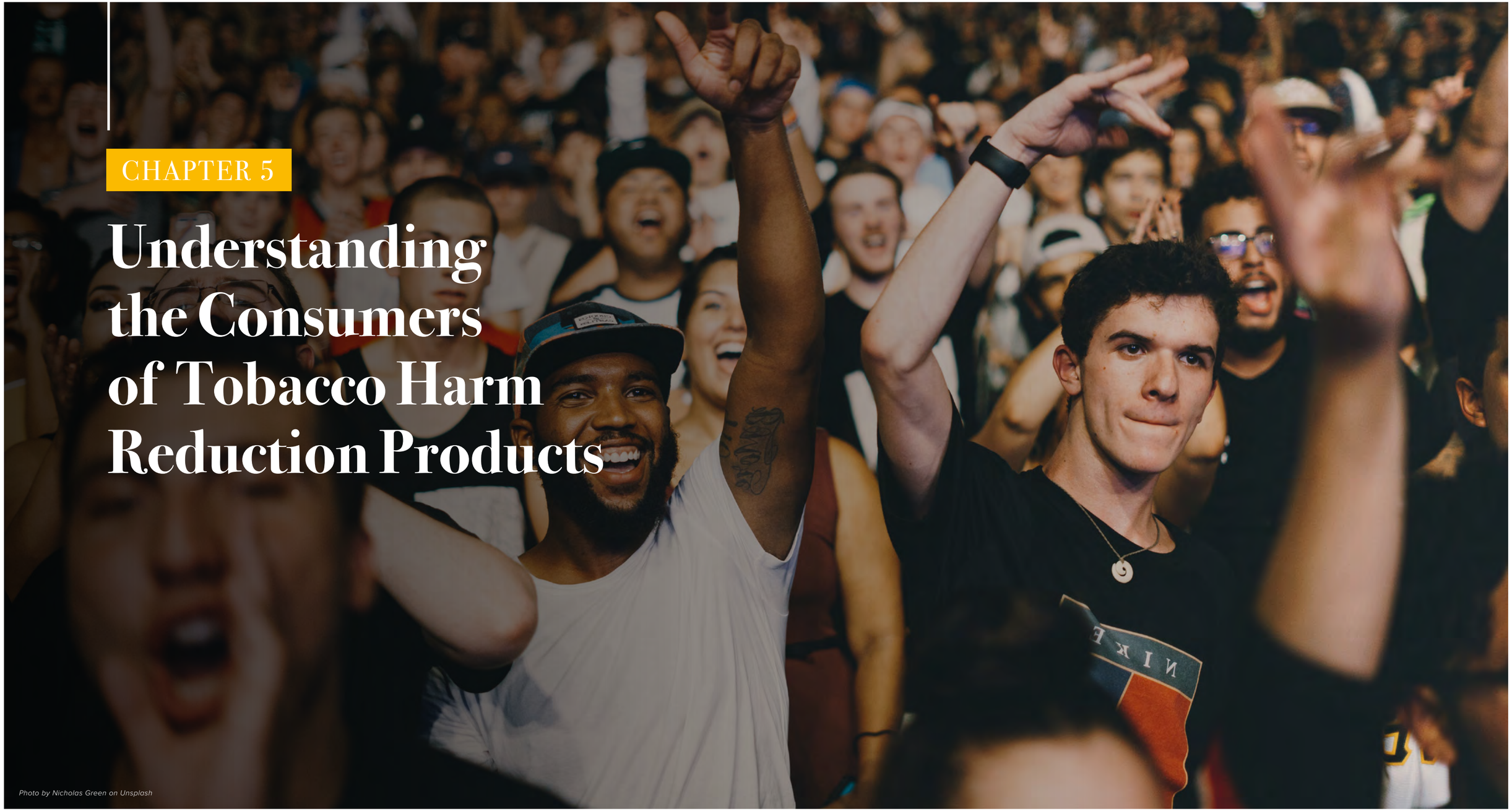
CHAPTER 5

Understanding the Consumers of Tobacco Harm Reduction Products



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WHO ARE CONSUMERS OF TOBACCO PRODUCTS AND WHY ARE THEY DEHUMANISED?

In 2015, the World Health Organization (WHO) reported an estimated 1.1 billion consumers of tobacco products, of which the majority smoke cigarettes.[1] It has since stated in 2018 in its global report on trends in prevalence of tobacco use 2000-2025 third edition, that overall global tobacco use was 1.337 billion.

In this report, the WHO also pointed out "most tobacco-related deaths occur in low- and middle-income countries, areas that are targets of intensive tobacco industry interference and marketing."[2] The number of cigarette consumers is growing, particularly in middle- and low-income countries.

Despite the best efforts of health professionals and regulators in the area of tobacco control, the total number of smokers is expected to reach 1.6 billion by 2025.[3]

In addition, most new smokers come from disadvantaged socio-economic groups, and not only are they more likely to smoke, but they smoke more and are more heavily addicted. Particularly worrisome is that children growing up in disadvantaged households are more likely to start smoking themselves and to start at a younger age.

Second hand smoke inhalation is also more prominent in these groups.[4][5] It is worth remembering the stark fact that tobacco was the root cause of 100 million deaths in the 20th century.

Approximately 4.9 million people die from tobacco related illnesses each year. Future projections state that most of the 150 million deaths from smoking expected worldwide in the next 20 years will occur in people who are consuming cigarettes today. Most of these deaths are preventable.

THE NEED FOR CONSUMER AND PATIENT-CENTRIC DISCOURSE

Epidemiological data can easily dehumanise the individuals involved. Therefore, when finding out who the tobacco consumer is, it is critically important to maintain a person or patient-centric approach.

Dr Don Berwick, former Administrator of the Centers for Medicare and Medicaid Services (CMS) in the USA coined the phrase "patient-centered" health care.[6] He did this in response to a trend, commonly seen in modern hospital settings, in which patients become numbers within a health care system, and the environment and health workers can become almost "patient-hostile". Dr Berwick was perfectly correct to castigate such a trend. He articulated three maxims of patient-centred care that are also worth applying to the harm reduction debate[6]:

(i) "The needs of the patient come first."
(ii) "Nothing about me without me."
(iii) "Every patient is the only patient."

Expanding on the last maxim, Dr Berwick explained: "The experience (to the extent the informed, individual patient desires it) of transparency, individualization, recognition, respect, dignity, and choice in all matters, without exception, related to one's person, circumstances, and relationships in health care."[6]

When it comes to tobacco consumption, it makes sense that maintaining a consumer-centric approach will facilitate a better understanding of the rights to health of each individual tobacco product consumer. In order to do this, however, we first need to have a better grasp of the different types of tobacco consumers.

JULY 2020 CONSUMER PERCEPTION SURVEY: TOBACCO HARM REDUCTION PRODUCTS

It is precisely because the consumer voice is generally ignored, that global country market research, survey and business consultancy firm Kantar was commissioned to conduct a multi-country study in July 2020 to examine the usage and attitudes towards vaping, heated tobacco products and cigarettes.

The 2020 fieldwork was undertaken in six countries: Indonesia, Mexico, Canada, Italy, Japan and Spain. The survey targeted people who used e-cigarettes and/or other tobacco products for inclusion. Independent consumer insight experts 56 Degree Insight provided support on the survey design, analysis and reporting of results.

Questions covered a range of topics including current usage and perceptions of products, including attitudes towards quitting smoking and methods used to help giving up. Some of the highlights from the key findings of the Kantar survey are:

> **"Compared to other products (i.e. heated and oral tobacco), people are far more likely to use vaping for the purposes of helping to cut down on smoking."**

USAGE AND MOTIVATIONS

A large percentage of those who smoke cigarettes, vape or use heated tobacco products use multiple products. For example, across all six countries combined, 41% of those who vape also used heated tobacco products.

Many of the people who vape also smoke cigarettes, which was particularly evident in Italy and Spain where over half of vapers smoke more than six cigarettes per week.

While one of the top reasons for choosing to use e-cigarettes is to help smokers cut down on the amount they smoke, only around a third of all vapers across the six countries opt for this. Similar proportions choose to vape because they like the taste or find it relaxing or enjoyable.

In all six countries, most of those who were vaping to help reduce smoking had tried quitting on several previous occasions. The most common approach they used in their previous attempts was 'cold turkey'.

Notably, only a very small percentage of vapers in all six countries took up e-cigarettes after a health professional advised them to do so. In these cases, they only received this advice after asking for it. Nevertheless, compared to other products (i.e. heated tobacco products), people are far more likely to use vaping for the purposes of helping to cut down on smoking. Conversely, they are more likely to use heated tobacco products to protect others from second-hand smoke.

USE AND APPROVAL BY OTHERS

There was a significant difference in the usage of cigarettes, vaping and heated tobacco products among family and friends between the countries included. The variance was generally highest in Indonesia and Mexico, but lowest in Japan.

Levels of approval also broadly reflected levels of usage by family and peers. Overall, Indonesia and Mexico indicated the most positive approval for all of the products.

In general, while vaping receives higher approval ratings than smoking cigarettes, using heated tobacco products or oral tobacco products, it is important that a large percentage believed a significant part of the population would disapprove of vaping. The proportion expecting disapproval among peers was highest in Canada.

PERCEPTIONS OF RISK

Overall, while, more people over the six countries combined believe that e-cigarettes are less harmful than tobacco cigarettes, a significant minority do not consider this the case. Indeed, over all about two-fifths (41%) of those interviewed considered e-cigarettes to be equally harmful or more harmful than tobacco cigarettes.

The percentage who consider e-cigarettes to be equally or more harmful than cigarettes is significantly higher in Indonesia and Canada, but lower in Japan. Correspondingly, a large percentage perceives several health risks linked to vaping. These are respiratory issues and addiction in particular, but some concerns over harmful ingredients, heart issues and cancer also exist.

About half of those interviewed across the six countries were aware of vaping-related issues in their country or elsewhere. Reflecting the other findings, this was highest in Canada and Indonesia, where there was a higher level of concern that vaping units had used illegal ingredients.

Overall, participants regarded heated tobacco products as having a similar range of health risks to vaping. Their health concerns were mostly associated with respiratory issues, especially among participants in Canada and Indonesia.

A notable perception by participants in all six countries was that the harm from smoking cigarettes was attributed equally to the nicotine and the tobacco burning.

THE JULY 2020 TOBACCO HARM REDUCTION CONSUMER AT A GLANCE

Although many vapers currently use e-cigarettes as an aid to cut down on smoking cigarettes, this is not always the case with users choosing to vape. They indicate a diversity of other reasons such as enjoyment or relaxation while continuing to smoke cigarettes and/or use other tobacco products.

Overall, while vaping is more likely to receive approval from peers and family than smoking cigarettes or using heated tobacco products, it is noteworthy that many vapers expect to receive disapproval for using e-cigarettes. This applies more in some countries than others do (e.g. in Canada, 33% stated that the general population disapproves of vaping).

It seems that there is uncertainty around understanding the risks associated with vaping, as up to 50% of users perceive the risks of vaping to be similar to smoking cigarettes. This lack of clarity – on the source of harm when smoking cigarettes – may be partially explained by vapers that are as likely to perceive the harm as originating from the nicotine as from the burning of tobacco.

Overall, these results suggest that more needs to be done – to raise awareness of the true risks and sources of the risks associated with smoking cigarettes and using other tobacco products – and how these truly compare with the more limited risks associated with vaping. It should be a priority to correct these misperceptions.

SOME CONSUMERS NEED NICOTINE MORE THAN OTHERS DO

We need to empathise with those consumers who feel that they cannot function without smoking. While these people come from all levels of society, certain groups have a particularly high prevalence of smoking. They include low-income individuals, manual labour workers, prison inmates and those with psychological problems.

Mental health problems. Consumers with mental health problems are much more likely to smoke, particularly those with psychotic disorders:

- Up to 80% of people with schizophrenia smoke[7];
- People with adult attention deficit disorder (*ADD*)[8], eating disorders and substance abuse disorders[9] are more likely to be smokers.
- 70% of people with psychotic disorders who live in mental health institutions, smoke. More than half of these smoke heavily, defined as more than 20 cigarettes per day.[10]
- In the UK, it has been found that people with depressive episodes and neurotic disorders (such as phobias or obsessive-compulsive disorders) are twice as likely to smoke as those with no neurotic disorder.[11]

Prisoners: Almost 80% of prison inmates in England and Wales smoke.[12]

Labour settings: Routine manual labour is linked with higher smoking prevalence.

Manual labourers consume an average of 15 cigarettes per day, compared with smokers in managerial and professional groups who consume 12 cigarettes per day.[5]

Photo by Nicholas Swanson on Unsplash

DO CONSUMERS WANT TO QUIT SMOKING?

Worldwide research shows that approximately 70% of tobacco users want to quit eventually. For example, in the United Kingdom, around two-thirds of smokers, no matter what social group they come from, want to stop smoking.[10] Around half of those with mental health problems want to quit smoking.[13]

CONSUMERS CAN FIND IT EXTREMELY DIFFICULT TO STOP SMOKING

Health professionals regularly witness the anguish that patients who decide to quit smoking experience. I remember, as a boy, watching my own Dad lying on the sitting room floor, white as a sheet, as he tried to quit cold turkey. He finally succeeded in quitting after seven attempts, which is more or less the average number of failed cessation attempts that smokers who decide to quit, experience.

When I worked in a large academic hospital, I saw many patients with severe chronic obstructive pulmonary disease (COPD) – due to smoking – that would come in to the emergency ward for urgent care. After half an hour of receiving intravenous infusion and inhalers to help dilate their constricted airways, I found it alarming that some of these smokers used the first opportunity after recovery to go outside and light up.

We need empathy when considering the plight of those who try to quit smoking. Nicotine withdrawal symptoms are not for the faint-hearted. These can include depression, anxiety, irritability, difficulty concentrating, insomnia, restlessness, headache and weight gain.[14]

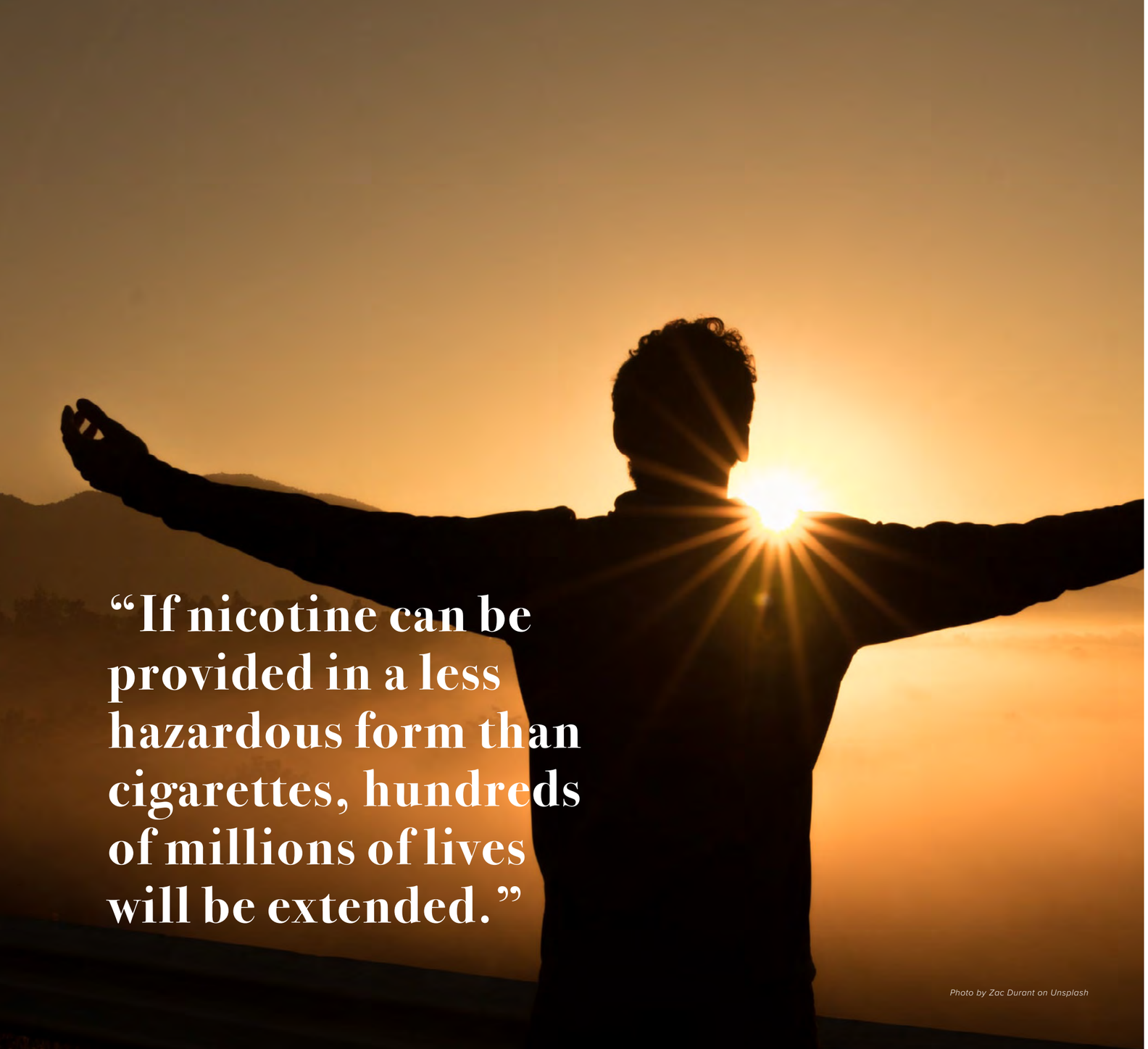
The American Psychiatric Association actually identifies nicotine withdrawal as a psychiatric disorder.[14] These withdrawal symptoms cause most smokers who attempt quitting to resume daily smoking. Most smokers admit that it is not only the nicotine they miss, but also the rituals and social aspects of smoking.[15][16][17]

The US Department of Health and Human Services considers tobacco dependence to be a chronic disease, saying, "The majority of users persist in tobacco use for many years and typically cycle through multiple periods of remission and relapse."[18]

The statistics of failed quit attempts are discouraging in themselves. In any given year, although more than 70% of smokers want to quit, only 44% actually attempt to quit and merely about 4 to 7% succeed.[19][20]

> **"Giving up smoking is the easiest thing in the world. I know because I've done it thousands of times."**
> *– Mark Twain*

Perhaps we need to redefine successful quitting. We should not issue a rigid dichotomy of "quit or not quit". Prochaska et al.[21] suggest that quitting is a process or series of successes that shifts the smoker from "no thought of quitting" to an eventual tobacco-free life. Many patients need a "quitting roadmap" rather than just a stop sign. Sometimes smokers use this well-travelled road repeatedly during every quitting attempt.



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PUBLIC HEALTH POLICIES DO NOT ADDRESS THE HARM TO SMOKERS WHO CANNOT QUIT

It is unfortunate that the broader public health community has never taken tobacco harm reduction (THR) measures seriously. This is despite compelling evidence supporting such measures and submitted by renowned bodies such the Royal College of Physicians (RCP) and the Institute of Medicine (IOM). It is vital to consider harm reduction strategies and a subtler redefinition of quitting, as public health policies show little or no support for those who are in between failed quitting attempts. Health professionals should see the prevention of further harm to the health of these smokers as a key priority.

> **"The research and development, marketing and promotion of significantly lower risk nicotine products should be at the top of the public health agenda."**

We know that nicotine itself is not especially hazardous, and that the main reason people smoke is because of addiction to nicotine. If nicotine can be provided in a less hazardous form than cigarettes, hundreds of millions of lives will be extended and significant public health care expenditure avoided.

General harm reduction is a fundamental component of everyday life and a cornerstone of medical practice. Unfortunately, in the case of tobacco, these principles have not been applied. At the very least, the research and development, marketing and promotion of significantly lower risk nicotine products should be at the top of the public health agenda. This will help smokers who cannot quit reducing the harm that smoke is doing to their health.

CONSUMER ACCEPTANCE OF HARM-REDUCED NICOTINE PRODUCTS

As the Kantar 2020 consumer survey suggests, multiple countries worldwide are showing increased acceptance of THR products. Both the public health community and nicotine product manufacturers need to ask the pertinent "why" and "what" questions. Consumer acceptance of nicotine products will depend on several factors. While there is inadequate research or scant understanding to date, these factors include:

- Social acceptability of the product – especially in replacing the rituals –, group bonding among smokers and enjoyment of cigarettes.
- The ability of the product to relieve nicotine withdrawal symptoms – most likely by delivering an adequate dose of nicotine swiftly and for long enough to manage any cravings.
- Cost of the product.
- Availability – both geographically and in terms of widespread distribution and ease of access.
- Access to multiple brands of products.
- Overall consumer satisfaction (e.g. based on taste, product functionality and the "hit" derived etc).
- Beliefs regarding the safety of alternative nicotine products – consumers have long believed that nicotine is the harmful agent in cigarettes and that it can cause heart disease, cancer, respiratory ailments, and other tobacco-caused illnesses.
- Smokers are sceptical that nicotine replacement therapy (NRT) will work, yet they vastly overestimate their likelihood of success in quitting. This overestimation makes smokers less likely to initiate NRT use and be more pessimistic about its efficacy. This is especially true if they have previously used it during an unsuccessful quit attempt. Both of these factors rein in NRT's full potential in the population.[22][23]

HEALTH COMMUNICATION AND LITERACY

Inadequate levels of communication with consumers are at the heart of many of the problems related to tobacco control. This is also the biggest single reason for the "orphan status" of THR. Consumers are often unable to make an informed choice between different products as an alternative to cigarettes. This is simply because they have not been educated about the relative risks of the products or their general health literacy is inadequate.

Health communication *"consists of a wide variety of activities, both purposive and unintended, that inform and influence decisions that affect the individual and the public's health. Health communication is a hybrid discipline that draws from principles and research developed from the practices of marketing, public relations, journalism, and communication as well as clinical medicine and public health. It is the study and use of both mediated and person-to-person messages processed at multiple ecological levels, focused on health-related influences and outcomes."*[24][25]

Without doubt, the current quality of health communication regarding the relative risks of tobacco products and the benefits of THR is poor. Health professionals are in a good position to help rectify this deficiency.

Health literacy refers to a person's capacity to obtain health information, process it and act upon it. A strong body of evidence indicates that poor health literacy leads to less healthy choices, riskier behaviours, poorer health, more hospitalisations and higher health care costs. Significant numbers of people in both developed and developing countries have poor health literacy skills. For example, in the USA, it is thought that about 90 million adults – half of the adult population – lack the literacy skills needed to use the US health care system effectively.

Applied to tobacco and nicotine products, there is currently what I describe as *"nicotine illiteracy"*. This is, among not only consumers, but also even the health professionals looking after them. The current understanding and knowledge of nicotine risks, benefits and potential role in harm reduction can greatly be improved.

Ways in which to do this could include[26]:

- Better training of health professionals in tobacco and nicotine science;
- Providing simplified, more visually appealing written materials;
- Using technology-based communication techniques;
- Educating educators and health care providers; and
- Providing assistance in navigating health care systems.

STAKEHOLDER ENGAGEMENT

Key stakeholders are the ones with significant influence on, or who are significantly affected by, the outcome of a debate or work in a connected area. Tobacco product consumers are *key stakeholders* in the development of policies, products and the science of the products they use, yet they rarely sit at the same table as lawmakers.

The same applies to the current lack of substantive discourse between the public health community and the relevant consumers on THR. While there are NGOs and other member-based societies that represent the views of the consumer, none is involved in serious engagement of all the individual stakeholders or groups with a vested interest in the outcome of the debate.

"A man may learn wisdom even from a foe." – Aristophenes

It is enlightening to study the history of the international campaign that focuses on implementing better treatment for HIV/AIDS patients. Until the 1990s, many HIV patients found it very difficult to access treatment with anti-retroviral therapy. With an exorbitant annual cost of these treatments, this represented a seemingly insurmountable problem for public health. Many AIDS experts say that the success achieved in making HIV/AIDS treatment more affordable and accessible was based on patient-led activism.

HIV/AIDS patients were unwilling to accept the status quo in which they did not have a seat at the table of public health. Public health officials decided policies and even products for them, instead of discussing these issues with them. In a remarkable turnaround, these patients managed to raise awareness for their illness, mobilise resources and increase access to treatment. Perhaps tobacco consumers can follow this example and advocate for better cessation and harm reduction policies and resources.

CONSUMERS AND THEIR HUMAN RIGHTS

A profoundly important aspect of the THR debate that has almost been forgotten is that consumers have a fundamental human right to health. The Universal Declaration on Human Rights (UDHR)[27] affirms that "everyone has the right to a standard of living, adequate for the health and wellbeing of himself and his family, including… medical care and necessary social services…"

Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) further embodies the human right to health.[28][29]

This human right was utilised successfully in the struggle to gain access to treatment for patients suffering from HIV/AIDS. THR could well be the next area of application.

Certainly, the right to health in the ICESCR states quite clearly that it is *"the right of everyone to the enjoyment of the highest attainable standard of physical and mental health."*

Furthermore, Article 12 of the ICESCR requires that countries help to realise this right for its citizens by taking steps to ensure:

- "The improvement of all aspects of environmental and industrial hygiene;
- The prevention, treatment, and control of epidemic, endemic, occupational and other diseases; and
- The creation of conditions which would assure to all medical service and medical attention in the event of sickness."

It follows then, that countries should provide access and information to promote the autonomy of those who are most vulnerable and least able to manage their own health behaviours. THR clearly falls within this category, since access to less hazardous tobacco products would help individuals limit the harm of tobacco use, without completely eliminating its use.

Here again, the issue arises of individual rights versus societal rights. If this right is applied to harm reduction, it does pose a problem. Harm reduction might indeed increase the number of users at the population level. However, Kozlowski et al argue that this should not be the basis on which we judge a human rights-based approach. The right to health focuses on the autonomous individual; it is not a right to public health.[30][31]

Applying this human right to health in the WHO Framework Convention on Tobacco Control(FCTC), it is clear that the framework does not adequately address this. This is despite the fact that the WHO has recognised that nicotine addiction is a disease and that *"nicotine dependence is clearly a major barrier to successful cessation."*[32]

It is hoped that eventually, the principle of harm reduction and the fundamental human right to health of all tobacco consumers will become part of not only the tobacco control debates, but also that harm reduction will be addressed in detail, as a pillar of the FCTC.

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CHAPTER 6

Regulatory Aspects of Tobacco Harm Reduction

After at least 50 years of public health-led tobacco control, the most hazardous nicotine-containing products, cigarettes, are the least regulated while medicinal nicotine, the least hazardous, are the most regulated. Not only is this illogical; it is not in the best interest of the individual patient or public health in general.

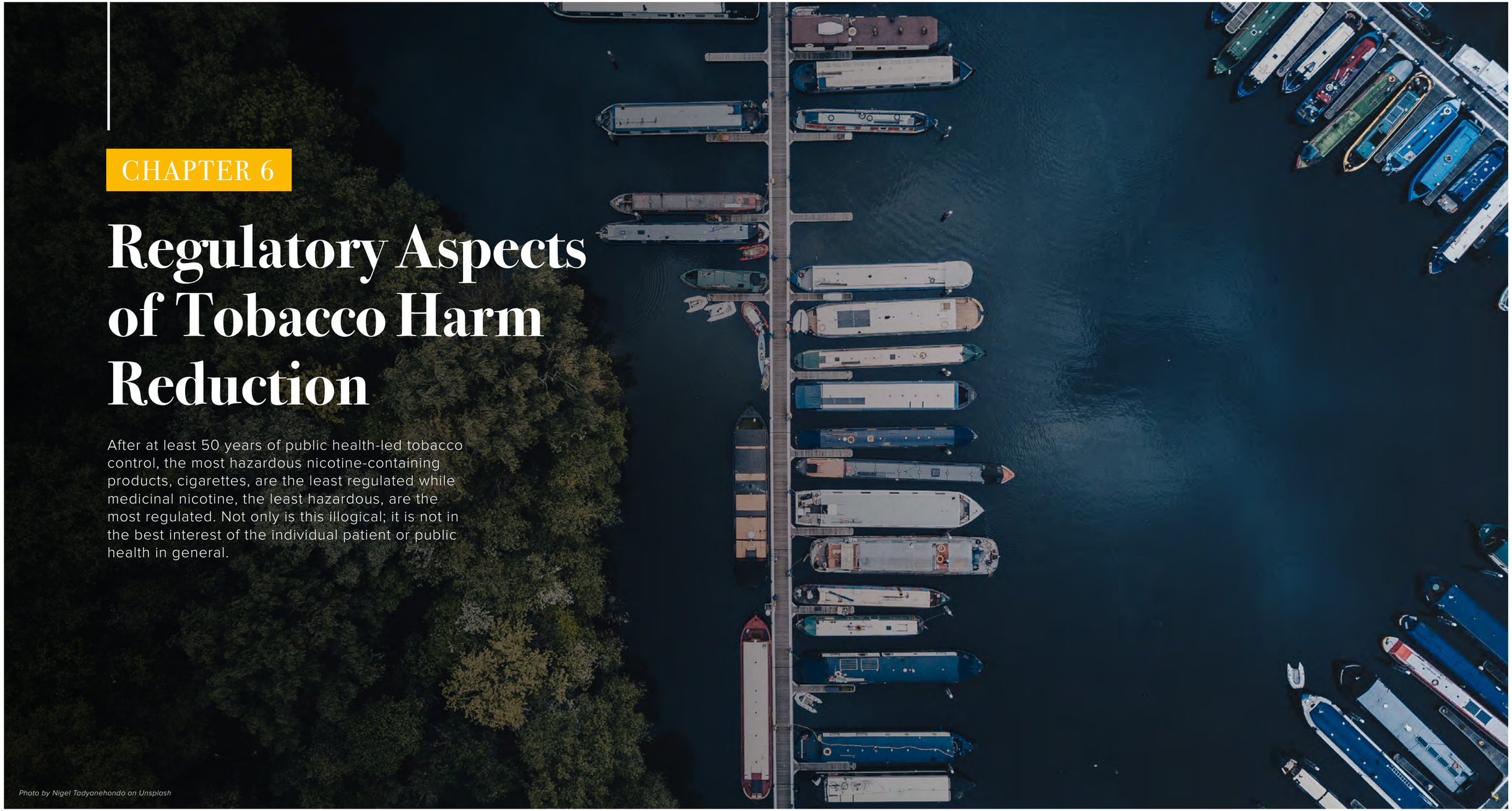

Photo by Nigel Tadyanehondo on Unsplash

“A major change is needed in the way all tobacco and nicotine containing products are regulated to encourage smokers to quit, or switch to less harmful products.”

Photo by Daoudi Aissa on Unsplash

CURRENT REGULATION HINDERS TOBACCO CESSATION AND HARM REDUCTION

Smoking cessation is a great challenge for everyone – for smokers wanting to quit, for the health professionals helping them, for the health care system and even for the regulators. The fact that those who quit may experience significant physical, emotional and psychological withdrawal symptoms has already been noted.[1]

We also know that although more than 70% of smokers want to quit, only 4 to 7% succeed.[2][3] The rituals involved in and social aspects of smoking make quitting even more difficult.[4]

Against this background, it would be reasonable to assume that nicotine regulation – both at international and national levels – should be formed in such a way as to[5] support and enhance the smoking cessation and harm reduction structures, products and services.

Unfortunately, this is not the case. It is for this reason that the first three sections of this chapter focuses on the objectives for regulation, e-cigarette regulation and elements of an appropriate regulation system.

OBJECTIVES FOR REGULATION

Fundamental principles for tobacco and nicotine regulation should include:

- Science-based;
- Proportionate to the degree of risk to the consumer;
- Most restrictive regulations applied to the most harmful products;
- Least restrictive regulations for the least harmful products; and
- Protect youth from initiation or use of any tobacco or nicotine product.

Abrams et al.[5] call for regulation that will "save smokers" lives now while simultaneously protecting youth. The key challenge is to implement policies that maximise the net flow away from smoking and toward the use of safer products, or to no use. A balance can and must be found to protect youth without discouraging cleaner nicotine use by smokers unable or not wishing to quit their nicotine use.[6][7][8][9][10][11]

In tobacco control, it is difficult to achieve this balance. This is because the public and consumers need to receive clear risk differentiation and risk communication about various product categories. At the same time, companies need to be incentivised to create new, less harmful products.

Unfortunately, even in cases where there is a wealth of epidemiological evidence, less harmful products are still banned or discredited. Consider the example of Swedish snus. The World Health Organization (WHO) still publicly describes Swedish snus as "not a safe alternative to smoking", even though there is ample evidence to the contrary.[12][13][14][15] Based on this advice, many countries still ban Swedish snus.

The reason behind this scepticism is the mistrust in the tobacco industry. It has been accused of undermining tobacco control and misleading consumers about the true dangers of smoking cigarettes – for details, see Royal College of Physicians, Chapter 9, p. 135-45.[11]

It is encouraging that the US Food and Drug Administration (ASFDA) granted Swedish match the "modified risk order" for eight general brand snus products. If snus can help prevent tobacco-related disease and preventative death, regulation should allow for it, backed by sound science.

E-CIGARETTE REGULATION

One of the fastest growing nicotine-based, non-combustible product categories is the electronic cigarette, also called e-cigarettes. Another phrase for these products is one the WHO calls "electronic nicotine delivery systems" (ENDS).

The preferred regulatory frameworks for this category should achieve the following objectives:

- To ensure that e-cigarettes and vapour products are as safe as possible without compromising their appeal as alternatives to smoking; and
- To ensure that they are not marketed in a way that increases total population harm, including through recruitment of young people or non-smokers who would not otherwise smoke.

Note that the aim should not be to prevent all young people from using e-cigarettes. There may indeed, be a significant health benefit in young people using e-cigarettes if this is an alternative to smoking or other harmful behaviour.

Regulators should aim to achieve a "sweet spot"[5] of regulatory intervention that builds confidence among consumers and removes rogue operators and defective products from the market. On the other hand, such an intervention should not impose costs, burdens and restrictions that crush the smaller players, radically change the products available and obstruct innovation. Figure 1 below relationship illustrates the concept of this relationship.

CONSUMER VALUE FROM E-CIGARETTE REGULATION (CONCEPTUAL)

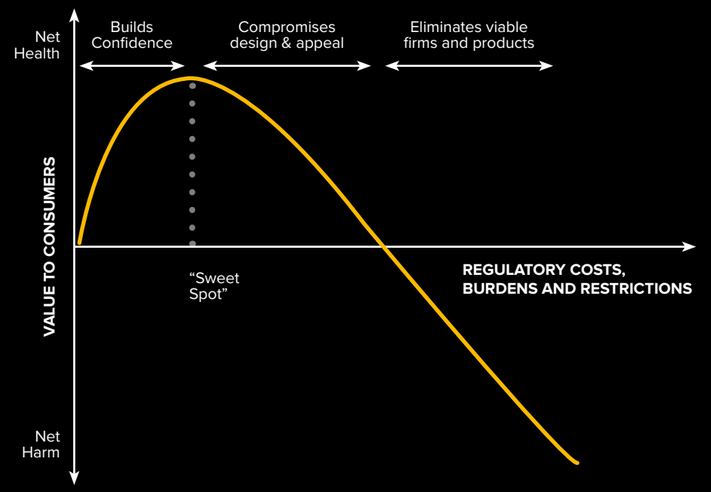

Figure 1: Finding the sweet spot

ELEMENTS OF AN APPROPRIATE REGULATORY REGIME

The most advantageous regulatory regime would strike a subtle balance between protecting users, non-users, bystanders and limiting the risks of harmful unintended consequences.

A reasonable proportionate regulatory regime (the "sweet spot") may cover many of the following elements, and it may develop over time.

While the following list is not intended to be comprehensive, it outlines the main regulatory areas:

Liquids

- Obligation to use pharmaceutical grade nicotine and diluents in liquids;
- Minimum requirement that flavours are food grade;
- Place a ban on ingredients known to be carcinogenic, mutagenic, reproductive toxicants or respiratory sensitisers;
- Confirm purity standards or thresholds for contaminants in liquids;
- Products should adhere to their descriptions and contain the stated content of nicotine and flavours;
- Adopt a quality management standard for child resistant containers – for example, possibly the ISO8317; and
- Feature a use-by date.

Companies

- Companies should provide their registered address and identify "responsible person(s)";
- A quality management standard e.g. ISO9000 should be in place; and
- Products should contain appropriate markings to provide ways of identifying and recalling products.

Devices

- Electrical safety specifications should ensure that chargers and battery combinations are safe;
- There should be a heat safety specification;
- Materials used in devices should be approved for use with food; and
- Possible operating thresholds for devices should be considered, e.g. to have a maximum temperature.

Marketing and Advertising

- Claims must be true, not misleading and supported by evidence;
- It should contain proportionate warnings related to toxicity and addictiveness;
- It should restrict themes and media attractive to under-25s;
- It should restrict sales to adults; and
- As with any age-sensitive product, there should be an age-verification for online and shop sales

Testing

- Any testing regime should support the regulatory objectives and regulatory decisions; and
- Testing should focus on quality of liquids and devices, rather than vapour measurements.

Vaping in public places

- Banning vaping by law or a blanket prohibition is totally unwarranted – the case for banning smoking by law rests on material harm to others;
- There are many places, times, events and circumstances where vaping may be reasonable, desirable or commercially valuable – a blanket ban should therefore, not rule out such circumstances;
- Premise owners and operators should decide their policy and make informed judgements [including the welfare value to vapers and smokers]. They should also clarify whether vaping is permitted or not;[16] and
- Vapers should approach vaping in public as a matter of etiquette with due regard for others.

WHERE POOR REGULATION CAN HINDER, RATHER THAN HELP

POOR REGULATION IS THE PRIMARY RISK TO PUBLIC HEALTH

The primary risk to the otherwise highly positive developments with e-cigarettes is poor and excessive regulation. At the heart of the regulatory challenge is a "double negative" – being tough on e-cigarettes is being tough on the competitive alternative to cigarettes.

There is a danger that loss-averse regulators and officials will place excessive focus on the residual risks associated with vapour products, but in doing so render them less effective and appealing as alternatives to smoking. In taking this stance, they will in fact, increase total health risks through the unintended consequence of additional and continuing smoking.

> **"There is no reason to regulate alternative nicotine delivery system products as something they are not – as tobacco products, poisons or medicines."**

UNINTENDED CONSEQUENCES OF REGULATION WILL DOMINATE

The following table illustrates how regulatory measures may possibly have unintended harmful consequences – protecting the cigarette trade and resulting in more smoking than there otherwise would be. This is cause for concern, since these effects are likely to far outweigh the intended consequences of most regulatory proposals under development today.

PLAUSIBLE UNINTENDED CONSEQUENCES OF EXCESSIVE REGULATION

POLICY	PLAUSIBLE UNINTENDED CONSEQUENCE
HIGH COMPLIANCE COSTS OR BARRIERS TO MARKET ENTRY	A loss of product diversity means consumers are unable to personalise the vaping experience or find products that they enjoy. Thus, users may find the experience less satisfactory, and continue to smoke or relapse. Alternatively, a black or grey market of possibly unregulated products could develop, destroying responsible domestic producers creating cross-border trade to meet demand. Cumbersome or expensive authorisation regimes also make innovation more difficult and expensive. Therefore, there will be less innovation and experimentation with consumer preferences.
PROHIBIT HEALTH OR RELATIVE RISKS CLAIMS	This denies smokers real world truthful information about relative risk and may cause more smoking. It is uncontroversial that e-cigarettes are safer than smoking – the debate is over where in the range 95-100% less risky. This erects high and unnecessary regulatory barrier to truthful communication – and therefore obscures the most important consumer benefit from consumers. Those determining whether a health claim should be allowed are often "loss averse" – concerned about what might go wrong if they allow a claim to be made. However, they rarely pay equivalent attention to the "false negative" error: the lost benefit arising from rejecting a valid claim.
RESTRICTIONS ON ADVERTISING, PROMOTION AND SPONSORSHIP	Reduces the ability of e-cigarette brands to compete with cigarettes (the market incumbent) and diminishes means to communicate the value proposition to smokers. It may reduce ways to communicate innovation or build trusted brands. If subjected to excessive control products may become dull and sterile, diminishing appeal. Almost all e-cigarette advertising is a form of anti-smoking advertising provided without any call on public funds – it would be perverse to stop this and spend public money instead.

POLICY	PLAUSIBLE UNINTENDED CONSEQUENCE
RESTRICTIONS ON NICOTINE STRENGTH IN LIQUIDS	Smokers are unable to sustain a satisfactory nicotine experience during the first stages of switching or while they are learning to vape. They then relapse to smoking or give up on vaping. Heavier or more dependent smokers may find e-cigarettes unsatisfying, so those most at risk are denied the products more likely to be effective. Restrictions may also drive users to black markets and/or home mixing with high strength liquids. This would also impede successful innovation for products like Juul, which use high strength e-liquids (~5%).
BANS ON FLAVOURS	All e-cigarettes and liquids are flavoured with something – and this forms a key part of the appeal. Many former smokers report switching to non-tobacco flavours as a way of moving permanently away from smoking. There is a significant risk that loss of broad flavour categories will cause relapse among e-cigarette users and fewer smokers switching. In addition, it may result in the development of DIY and black-market flavours – which may be more dangerous. Even with young people, there is the possibility that any attraction to flavours is an attraction away from cigarette smoking and may be beneficial, meaning a ban would be harmful.
BANS ON ONLINE SALES	Because vaping options are highly diverse, user density still quite low and technological evolution rapid, the internet-based business model is important. This will provide the greatest choice and convenience to users without needing thousands of shops holding very large stocks of slow-moving inventory. If users are forced to purchase from 'bricks and mortar' outlets but do not have a specialist shop nearby, they are likely to see their options limited and vaping relatively less attractive.

PLAUSIBLE UNINTENDED CONSEQUENCES OF EXCESSIVE REGULATION (CONT.)

POLICY	PLAUSIBLE UNINTENDED CONSEQUENCE
POLICY COMPLIANCE BURDENS AND OTHER COSTS – LEADING TO BLACK MARKETS	Black markets develop in response to restrictive or costly regulation or taxation. Black markets can compensate for poorly designed policy to some extent and they are likely to emerge as the TPD is implemented. However, they also cause harms through trade, transit and handling of high strength liquids, product quality, poor labelling, inferior packaging. They may exacerbate risks the policy is designed to mitigate.
HEALTH WARNINGS	Warnings should frame risk information that allows users to make informed choices. Alarmist health warnings, even if literally correct, can be misleading and misunderstood by the public. This has often been the case with smokeless tobacco (e.g. "This is not a safe alternative to smoking") Warnings do not adequately communicate relative risk and, therefore, understate smoking risks or downplay the advantage of switching. They may obscure much more important messages about relative risk compared to smoking that is not provided in official communications. Warnings about nicotine may exacerbate misperceptions about the (minimal) role of nicotine in causing disease.
LIMITS ON CONTAINER AND TANK SIZE	Such limits would make the vaping experience of vaping more inconvenient and less attractive to smokers. They require more filling operations and increase the likelihood of running out of liquid – creating circumstances for possible relapse. Poisoning risk is not normally managed by limiting container size (e.g. for medicines or alcohol).

POLICY	PLAUSIBLE UNINTENDED CONSEQUENCE
BAN SALES TO UNDER-18S	There is near universal support for this policy. However, US studies found that in areas where e-cigarette sales to under-18s had been banned, the decline in smoking was slower than in areas where it was not banned. However, it is worth noting that NRT is made available to people over 12 years in some jurisdictions – because young smokers also need to quit. It should not be assumed that 'harm reduction' should start at 18.
PRODUCT DESIGN RESTRICTIONS AND REQUIREMENTS – TESTING AND PAPERWORK	There are numerous subtle trade-offs in product design between safety and appeal and cost. For example, the perfectly safe product that no one wants to buy may be worse for health if it means more people smoke. Excessive design regulation can impose high costs, burdens and restrictions, slow innovation and drive good products and firms out of the market through 'regulatory barriers' to entry. Very high spec regulations will tend to favour high volume, low diversity commoditised products made by tobacco or pharmaceutical companies.Regulation can adversely reshape the market and reduce the pace of innovation.
BAN E-CIGARETTE USE IN PUBLIC PLACES	Diminishes value proposition of e-cigarettes to users and 'denormalises' vaping, a much less risky option, and so diminishes the appeal of vaping relative to smoking. It may promote relapse in existing vapers if they cannot maintain adequate nicotine levels or if they join smokers outside.

POLICY	PLAUSIBLE UNINTENDED CONSEQUENCE
CONTROLS ON "ADDICTIVENESS"	This would entail limiting the psychoactive impact of nicotine, for example, by controlling pharmacokinetics (PK), acidity, additives etc. This risks restricting the capability of e-cigarettes to replace cigarettes for some smokers, therefore, implying a trade-off in favour of reducing dependence rather than reducing serious disease. The problem of 'abuse liability' is why NRTs have not been that successful.
RAISE TAXES ON E-CIGARETTES	This reduces the financial incentive to switch from smoking to vaping unless the tax on smoking is also increased. But if these taxes are raised too high, it will tip users into other forms of unintended behaviour – accessing the black market, switching to rolling tobacco, or create cottage industries producing e-liquids in garages. It may also favour smoking cessation medications that are less effective on average, such as NRT (which in the UK actually receives an unjustified VAT discount).[17] Establishing a tax regime is costly for both authorities and manufacturers – those costs are passed on to consumers, which depresses demand and reduces the price sensitivity of users to increases in cigarette prices. If the tax is made risk-proportionate, it would likely to be too low to be worth the expense of collecting – so any tax on vaping is likely to be disproportionate by default.

THE RISK OF USER COUNTERMEASURES TO OVERCOME POOR REGULATION

Regulators do not have a free hand. Excessive regulation or laws that remove products from the market that users want, will result in users rebelling and legitimately undermining regulation they perceive to be harmful to their health or wellbeing. Implementing proportionate regulation is much better to avoid the development of unregulated black or grey markets and products being produced at home.

Photo by Steven Lasry on Unsplash

THE WORLD HEALTH ORGANIZATION VIEW ON E-CIGARETTES

The World Health Organization Framework Convention on Tobacco Control (WHO FCTC) defines itself as "an evidence-based treaty that reaffirms the right of all people to the highest standard of health". Given the challenges in nicotine product regulation, one may have expected that the WHO would attempt to correct these regulatory imbalances.

It could do this by recommending WHO member states to encourage, enable and facilitate the increased use of nicotine as a tool for both smoking cessation and harm reduction. Unfortunately, this opportunity has been lost so far.

The WHO has focused almost exclusively on cessation and with regard to E-cigarettes (ENDS), almost taken on an activist advocacy role. It is potentially at risk of misrepresenting and miscommunicating the relative risk and underpinning science of ENDS.[18]

The WHO's favoured approach is to classify these products as both medicines and tobacco and to apply the restrictive measure of the WHO's tobacco treaty (the Framework Convention on Tobacco Control).[19][20] In addition, it would also like to include these products in UN targets to reduce tobacco consumption by 30% by 2025.[21]

This would make it impossible to achieve this target by denying the most likely way of meeting it. As a result of this stance by the WHO, 53 of the world's top experts wrote[22] to the organisation in May 2014, imploring it to take a more constructive approach.

In November 2021, the WHO FCTC Parties will host their next Conference of the Parties (COP9) in the Netherlands (World Forum The Hague, 2021). This critically important policymaking gathering has the opportunity to address:

- Gaps in the FCTC and what aspects it needs to update.
- This restructuring applies specifically to harm reduction. While it is recognised in Article 28 of the FCTC, it urgently needs further specification and encouragement;
- Agreed actions that need to be accelerated, such as smoking cessation; and
- The need to include minority groups, women and evidence-based tax policies.

At COP 9, the WHO will hopefully embrace the opportunity to live up to its own mission statement.

"Given the challenges in nicotine product regulation, one may have expected that the WHO would attempt to correct these regulatory imbalances."

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CHAPTER 7

The Scientific Evidence for Tobacco Harm Reduction (THR)

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WHY THE EVIDENCE BASE FOR TOBACCO HARM REDUCTION IS IMPORTANT

In tobacco control, evidence-based policy is sacrificed too readily for policy-biased evidence seeking. Ideological and political factors, rather than sound science, often drive policy. Consider, for example, that some governments ban E-cigarettes, yet still permit the sale of traditional combustible cigarettes!

In reality, policymakers take the easy route, instead of using robust scientific methods to measure the public health costs and benefits of tobacco harm reduction products. Their usual way is to highlight the unspecified risks of a new THR product category, apply the precautionary principle and seek the most restrictive regulations possible to limit the access and use of less harmful nicotine products. It is frustratingly short sighted.

THE PRECAUTIONARY PRINCIPLE – MISUNDERSTOOD AND MISUSED

Much policy discourse has focused on applying the precautioning principle to recognise residual uncertainties in the ultimate health risks of smoke-free products. The obvious limitation with relatively new products is that it is impossible to have multi-decadal epidemiology. However, the precautionary principle requires disciplined application. For example, the European Union's interpretation[1] stresses the need for a rounded assessment that considers:

- Proportionality between the measures taken and the chosen level of protection;
- Non-discrimination in application of the measures;
- Consistency of the measures with similar measures already taken in similar situations or using similar approaches;
- Examination of the benefits and costs of action or lack of action; and
- Review of the measures in the light of scientific developments.

Of particular relevance in this list, is the requirement to assess the consequences of both action and inaction. In other words, it needs to consist of plausible harms that would arise from restricting what are likely to be far less harmful products in a market dominated by cigarettes.

There is no avoiding a risk assessment based on what is known. This means looking not only at the risks of the product, but also at risks that might arise from policies justified on supposedly precautionary grounds.

The risks of smoking are great and the poorly designed regulation of smoke-free products can easily increase smoking. For this reason, there should be a high bar to restricting safer alternatives. This should be based on uncertainty about future risks that are unknown, implausible, or likely to be far lower than for smoking.

> **"In tobacco control, evidence-based policy is sacrificed too readily for policy-biased evidence seeking."**

The precautionary principle is most relevant where risks are systemic, irreversible, accumulative or severe. This is why the principle initially gained prominence in environmental decision-making.

However, these conditions do not apply to smoke-free products, which pose individual risks that can be addressed through changing user behaviour or retrospective regulation.
It is unreasonable therefore, to apply the precautionary principle when forming tobacco harm reduction policy, if it has not been rigorously scrutinised and addressed all regulatory science aspects.[2]

WHY THE EVIDENCE BASE FOR TOBACCO HARM REDUCTION IS IMPORTANT

If THR can prevent tobacco-related death and diseases, more research is needed to help this strategy go mainstream and be embedded in global and national tobacco control policy.

The issue is what research objectives need to be met. Interestingly, the objectives listed in the pioneering 2001 report by the Institute of Medicine (IOM), Clearing the Smoke[3], still ring true:

- Manufacturers have the necessary incentive to develop and market products that reduce exposure to tobacco toxicants and that have a reasonable prospect of reducing the risk of tobacco-related disease;
- Consumers are fully and accurately informed of all the known, likely, and potential consequences of using these products;
- Promotion, advertising and labelling of these products are firmly regulated to prevent false or misleading claims, explicit or implicit;
- Health and behavioural effects of using potentially reduced risk products are monitored on a continuing basis;
- Basic, clinical and epidemiological research is conducted to establish their potential for harm reduction for individuals and populations; and
- Harm reduction is implemented as a component of a comprehensive national tobacco control program that emphasises abstinence-oriented prevention and treatment.

IS THERE AN AGREED GLOBAL RESEARCH AGENDA FOR TOBACCO HARM REDUCTION?

The World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC) repeatedly stresses that it is an "evidence-based" international treaty, implying that it receives research input from a multi-stakeholder, multi-national network. Even in its framework, it addresses research, surveillance and technology in specific articles (Articles 22–24 in Part IV of the FCTC).[4]

The question however, is whether there really is a sound, transnational research agenda for tobacco control (including harm reduction). The answer is, unfortunately, that there is not. Despite the fact that the 10th World Conference on Tobacco or Health (WCTOH) focused on developing priorities for tobacco control research[5], these have not been adequately funded or sustainably pursued. There were some exceptions, such as the National Institutes of Health program of support for global health research.[6]

Because of this lack of an internationally accepted research agenda, significant research gaps, particularly in the THR field, have developed in many countries. Nowhere is this more evident than in lower- and middle-income countries. Achieving FCTC goals on a global scale (including those related to cessation and harm reduction), can be achieved by conducting research in targeted settings and applying the results globally. The Council on Health Research for Development[7] describes this method effectively.

Photo by National Cancer Institute on Unsplash

PRIORITISING RESEARCH TO HELP SUBSTANTIATE THR BENEFITS

CESSATION

Smoking cessation remains the top priority for global public health. Article 14 of the FCTC states that all parties "shall take effective measures to promote cessation of tobacco use and adequate treatment for tobacco dependence."[4] There is little doubt that this objective has not been met, which will have deadly consequences for prospective quitters who do not have access or information on the most effective ways to quit.

Even in the USA, which is one of the most advanced developed countries in the world, the US Surgeon General's report indicates that cessation measures have not been effectively implemented.[8] A striking example is that despite smokers in the United Kingdom most frequently using e-cigarettes to quit, the more commonly available pharmaceutical approaches to cessation remain extremely ineffective, with quit rates averaging around 5-8% at the one-year mark.[9]

To correct this anomaly, it is imperative that health professionals and researchers clearly specify quit rates. Unfortunately, this data is not available in evidence-based medicine databases such as Cochrane Collaboration or even in the WHO's M-Power report. Without providing context to the relative failure of the traditional pharmaceutical approach to cessation, it is not possible to fully recognise the true value of tobacco harm reduction products.

Aside from the dearth of innovation in the smoking cessation space, the issue of access needs to be researched. Population-wide access to cessation should be a priority and only serious research can identify these gaps. An example of two groups where research is lacking is in people with mental illness and tuberculosis who smoke. In people with tuberculosis, smoking rates exceed 31% in some countries[10], while in those with schizophrenia, smoking rates often exceed 70%.[11] With no customised, accessible cessation programmes available for these groups, the result will be increased mortality rates due to tobacco use.

YOUTH USE

Another top priority for global public health is to prevent all youth initiation of nicotine. This includes prohibiting the sale of nicotine-containing products to those under legal purchase age, and preventing aggressive predatory marketing to youth. Research is needed to understand the context of adolescent behaviour better, as risk-taking in adolescence is normative. It results from competition between the strong socio-emotional network in the brain and the immature cognitive-control network.[12]

When it comes to any tobacco or nicotine product like an e-cigarette, risk-taking among teenagers may be the result of peer pressure or from seeking mood enhancement. If existing studies show that current youth use of e-cigarettes consists largely of experimentation, more studies will be needed to determine if this use leads to long-term adoption, which does not seem to be the case.[13]

Another important issue is the way in which studies measure current youth use of e-cigarettes, especially where they based prevalence on "any-past-30-day-use". It is vital to use more precise metrics to determine the frequency of use by youth and investigate the possibility of youth nicotine dependence. The same applies to the so-called "gateway theory" of e-cigarette use, which supposedly leads to cigarette smoking. Neither of these hypotheses has been adequately researched or proven.

IMPACT OF TAXATION AND FLAVOUR BANS

High taxes can dissuade consumers from using less harmful THR products and perversely, lead to ongoing consumption of cigarettes. Countries such as Saudi Arabia and the United Arab Emirates (UAE) impose the same tax schemes on THR products as traditional cigarettes.[14] Therefore, it is important to develop evidence-based taxation policies. Research is needed so that governments can objectively weigh the full benefits and costs of THR products on public health.

The same principle applies to flavour bans, which can negatively affect THR product uptake and lead to unintended public health losses. Continued surveillance is needed to monitor these potential negative effects. This would entail using comparisons between countries with and without bans on vapour products, to determine the population-level effects on harm reduction, cessation, and morbidity and mortality rates.

CONSUMER-BASED RESEARCH

Consumer-based research should become a necessity in the THR research agenda, especially during the Covid-19 pandemic. This research needs to determine the reasons for use, frequency of use, methods of use and presence of dual use for each THR product. Furthermore, it should include qualitative studies to understand the reasons for dual use.

In addition, longitudinal research is necessary to assess the efficacy of THR products to decrease tobacco consumption and cessation. It should also consider cultural differences to better understand reasons why smokers successfully switch from cigarettes to THR products.

CLINICAL STUDIES

The need for research does not stop there, however. Methodologically sound clinical studies are necessary for both short- and long-term use of THR products (e.g. snus, e-cigarettes and heated tobacco products) to verify their individual health impact.

These studies can be very useful in establishing better risk differentiation between the various THR product categories. In turn, this can hopefully lead to more proportionate, risk-based regulation and even taxation.

In particular, the scientific underpinning of the difference between combustible and non-combustible tobacco and nicotine products needs to be reinforced. Sourcing industry sales data – to compare and validate prevalence rates, THR product uptake and potential benefits of THR – have been underutilised so far.

POPULATION STUDIES

Whenever discussing the harm reduction potential of THR products, it is important to consider a series of individual and population-level policy issues. These include:

- The relative toxicity and risks of any THR product compared with cigarettes;
- Concomitant use of THR products and cigarettes with the potential for increased exposure to toxicants;
- Increased prevalence of THR product use due to increased uptake among those who would otherwise never use tobacco or nicotine;
- Maintenance of THR product use in consumers who would have otherwise quit and/or relapse to tobacco use; and
- Potential as a gateway product to or from cigarette smoking.

PRODUCT-BASED RESEARCH

Regulatory agencies require such research when companies apply to register their products or seek to achieve a modified risk status. This usually includes a risk assessment framework to measure reduced emissions, reduced exposure and, ultimately, reduced risk.

There is a growing consensus that nicotine delivery products involve a risk continuum and that most products that do not combust tobacco are likely to be substantially less risky to use than smoking cigarettes.

However, it is difficult to validate this fact scientifically. This applies especially to the diverse new categories of potentially reduced risk products such as e-cigarettes (ENDS), heated tobacco products (HTPs) and novel oral nicotine delivery systems.

Epidemiology is the gold standard to demonstrate the reduced risk of these products, but the problem is that it would take 25 to 30 years to collect data in relation to many of the chronic smoking-related diseases. Research requirements to assess these products include developing:

- Human-tissue based in-vitro assays of the pathogenesis of tobacco-attributable diseases;
- Human biomarkers of exposure and effect and the relationship between these biomarkers with disease risk;
- Methods and measures for short-term clinical and epidemiological studies, including consumer perception testing;
- Post-marketing surveillance or long-term studies to determine the impact of THR products at a population level;
- Behavioural science research to determine how people use the products by doing product testing in a realistic way;
- Chemistry studies to establish the contents of vapour or aerosol, as compared to those in cigarette smoke;
- Biological science studies to assess what the vapour/aerosol does to human cells in the laboratory. Again, this would need to be compared to the effect of smoking on human cells; and
- Population studies to determine how a particular product might affect population health, usually by using simulation modelling.

Photo by Lance Anderson on Unsplash

IDENTIFYING BOGUS SCIENCE

Several scaremongering articles specifically targeted at e-cigarettes have appeared in the media. In this section, we outline some pertinent issues related to e-cigarettes with their corresponding facts to help evaluate the quality of science. While one does not expect health professionals and others to become expert scientists, it is nevertheless useful to consider some of the complex aspects behind the science.

It is important to distinguish between hazard and risk.

Substances can be hazardous, but if the exposure to the body is low, there may be no risk or negligible risk.

RISK = HAZARD X EXPOSURE

TOXIC CHEMICALS IDENTIFIED IN E-CIGARETTE VAPOUR OR E-LIQUIDS

Assessing the extent of exposure: In this regard, question whether the studies show potentially harmful exposure of these "identified toxic chemicals" and whether they indicate the quantities.

Put another way, "the dose makes the poison". People are continually exposed to thousands of potentially toxic agents, but suffer no harm because the body has defences against most exposures up to a point. The amount of toxic chemical and the exposure it creates is important, and this needs to indicate a level that justifies concern.

For example, it seems that even smoking does not do lasting damage to life expectancy if a smoker quits before the age of 35.[15] So, for a smoker that started at age 15, that could mean 20 years of exposure to cigarette smoke without elevated mortality risk.[15]

Level of risk compared to smoking: Many studies fail to put any e-cigarette vapour exposures in proper context by not including smoking as a comparator in measurements or in reporting. Since smokers or ex-smokers overwhelmingly use e-cigarettes to replace smoking, it is pertinent to use smoking related-risk as the most important frame of reference to assess the health impact of these products. If a toxic chemical has been detected in e-cigarette vapour – but at a concentration 1 000 times lower than in cigarette smoke, that is an advantage to nearly all users.

Risk compared to other risks: Suppose you don't want a comparison with smoking, but want to compare vapour exposure to quitting completely or never smoking. Consider, however, that as virtually nothing is absolutely safe, you would need to establish what a fair comparison from everyday-life would be.

For example, if someone claims that e-cigarettes are not zero-risk, have they made valid comparisons with occupational exposure limits? They could also consider the levels of residual contaminants allowed in approved licensed pharmaceuticals or food to those in e-cigarettes.

Operating conditions: Were the measurements from the e-cigarette made in realistic operating conditions that real human beings would use? Many published findings have been based on overheating liquids and then measuring thermal degradation products such as formaldehyde. In reality, though, real vapers never experience these conditions because overheating e-liquid changes the chemistry and it tastes very unpleasant.

Appropriateness of substitutes used for risk: For example, calls to poison centres about e-cigarettes do not indicate a material risk. New products like e-cigarettes may result in increased calls to poison centres, but this does not indicate a material risk.

In absolute terms, such an increase could be trivial. As an example, an apparent rapid increase in the number of calls made to US poison centres – related to e-cigarettes and e-liquid – were, in fact, in line with increased media attention and a rapidly growing market. Such calls accounted for about 0.2% of all calls in 2014, with calls related to medicines and household cleaning fluids greater by the equivalent of multiplying by 100 (two orders of magnitude). Other inappropriate substitutes or proxies include public opinion polls and position taking by organisations.

Noble, but flawed, analogies: Studies sometimes use erroneous comparisons to suggest something is harmful in e-cigarette vapour because it has been found harmful elsewhere. For example, the aggressive and complex chemistry of ultrafine particles in tobacco smoke or diesel fumes may make them harmful, but the ultrafine particles in e-cigarettes (droplets of liquid aerosol) have completely different chemistry and physical characteristics. Therefore, the repeated claims that particles in e-cigarette vapour are harmful simply because of their size are unfounded.

REPORTS OF ADVERSE HEALTH EFFECTS FROM E-CIGARETTES

Was vaping the cause? One would need to determine whether there is proof that the vaping caused or contributed to the illness. For example, a few cases of lipoid pneumonia have been falsely attributed to e-cigarette vapour when e-cigarette use could not have been the cause. While one should not discard possible health risks related to e-cigarettes, caution is advised before claiming they caused a specific health effect.

Impact of prior smoking: If vaping patients develop an illness, one should wonder whether their history of smoking or other risk factors for disease have been adequately discussed as a possible cause. The risk of cancer and heart disease accumulated from smoking does not disappear when switching to vaping or quitting completely, but no one would say quitting smoking causes cancer. (The CDC notoriously used a long-term smoker in anti-vaping advertising and tried to blame her lung ailment on her recent vaping).

Evidence of harm: Ascertain whether the study is reporting the fact of a physical change in the body or brain, rather than a physical change that causes ill health or other harm. It is particularly important to take great care when considering neuroscience findings and claims relating to harm, brain damage or addiction. The brain responds to stimuli, which can be very compelling in MRI scan imagery. However, it does not mean that anything harmful is happening.

Impact compared to smoking: Question whether any negative health effects were set against the large gains in the reduction of major health risks for those switching from smoking to vaping.

Cell culture study: Establish whether the study involved cytotoxicity tests. Such tests, which are conducted on human tissue in the lab, are useful for comparing the toxicity of different substances under controlled conditions and can form part of a risk assessment.

However, the fact that cells are killed in these studies does not mean that the study has established a risk to human health, or that cells would be killed in the human body or cause cancer. This is because living cells in the body have various defences that cell cultures do not. Many in-vitro studies detect cell damage from exposures (e.g. to nicotine), but human studies or epidemiology have not detected any serious disease risk.

A further problem with cell studies is creating a realistic proxy for human exposure. If the study used exposure equivalent to 100 times higher than humans would experience for experimental reasons, we cannot draw conclusions about human health. We must thus ascertain whether a study's findings acknowledge or ignore the limitations of cell-culture studies. For further reading, Dr Konstantinos Farsalinos' blog provides some interesting reading on cell studies.[16]

Use of animals: Be wary of projecting results from animal studies to humans, especially if the animals are very dissimilar (e.g. rodents instead of primates). There are often huge differences between the toxicological susceptibility of different animals and physiology differences between humans and animals. Also, be cautious not to misinterpret certain types of animal studies, since some animals are specifically bred to have susceptibility to cancer for research purposes.

Whether you are a journalist, health professional or researcher, it is strongly advisable to read this article: Why journalists should stop publishing studies conducted with mice.[17]

Photo by veeterzy on Unsplash

YOUTH, E-CIGARETTES AND THE GATEWAY EFFECT

Properly defining use: When a study reports a high level of e-cigarette use (e.g. "16% of teens are using e-cigarettes"), it is pertinent to ascertain the following:

- Ignore the term "ever use". This is just an indicator of experimentation in young people and provides no meaningful information on risk;
- Question the frequency of use if the study quotes current use. A 2014 study in the US stated that 11.9% of high school students had used e-cigarettes in the last 30 days. However, 45.4% of these had only used e-cigarettes on 1-2 days while only 9.7% (of the 11.9% = 1.1% of high school students) had used the products daily;
- Smoking decrease, vaping increase: If increased vaping is substituting for decreased smoking, then it may be positive. In the US, teenage smoking rates fell rapidly as teenage vaping increased; and
- Level of nicotine-based use: US data suggest that only 22% used nicotine last time they used an e-cigarette.

Positive effects of increased e-cigarette use: Consider if the study authors have discussed whether e-cigarettes are displacing smoking, helping adolescents to quit smoking and even possibly be an alternative to never starting to smoke. In other words, have the authors failed to justify the idea that the gateway is an "exit" before discounting it?

Correctness of conclusions from apparent high coincidence between smoking and vaping behaviour: A study finds a pronounced association between two behaviours: A (vaping) and B (smoking), for example, the odds ratio. Four mechanisms can explain what is happening:

I. A causes B: This is a "gateway effect";
II. B causes A: This is "reverse causation". Young smokers try vaping to quit or reduce their dependence on smoking. Their e-cigarette use only happens because they are smoking.
III. C (a third factor or set of factors) causes both A and B: This is "shared liability" or "confounding". The same things that incline adolescents to smoke may also incline them to vape (e.g. parental smoking, rebellious nature); or
IV. Randomness: The sample does not represent the population.

Numbers 2 and 3 are positive explanations for the association, which may mean that smoking is being displaced by vaping.

Defining a gateway effect: Ask whether the study authors have hinted at a "gateway effect" without explaining what they mean. As an example, a harmful gateway from vaping to smoking arises when a person that would not have developed a persistent smoking habit in the total absence of e-cigarettes, uses e-cigarettes.

As a result, they develop a persistent smoking habit. The problem with this scenario (if it actually happened), is that it would be hard to detect a gateway effect. That is because it is necessary to know what would have happened in the absence of e-cigarettes – an issue that few researchers making this type of claim address.

Assumptions about prior behaviour as the cause of later behaviour: Question whether the authors have assumed that the order in which adolescents first try smoking and vaping is relevant in establishing a gateway effect. In reality, this is irrelevant.

What does matter, however, is if vaping causes smoking to develop into a persistent habit, when it otherwise would not have done. If someone vapes before smoking, it would need to be established what the individual would have done in a world without e-cigarettes and what the likelihood would have been of them smoking in that world.

CLAIMS THAT E-CIGARETTES KEEP PEOPLE SMOKING AND REDUCE QUIT RATES

Quitting success depends on the product, the user and their situation: When a study claims to show reduced smoking cessation among vapers, the key questions that need answering are:

- **What behaviour did the study examine?** Did it observe whether the e-cigarette users were trying to quit smoking? If not, then it is wrong to characterise the results as smoking cessation "efficacy";
- **Is there evidence of characteristics confusion?** Did those using e-cigarettes have the same characteristics as the overall sample? Alternatively, could they have been more highly dependent, less motivated, etc? Had they already failed at quitting some other way?
- **Is there reverse causality?** If e-cigarette use is higher in smokers than in recent ex-smokers, is that due to the smokers' preferences or the e-cigarettes?
- **How valid are the outcome measures?** Did the study limit outcome measures to "quit smoking" but fail to include "cut down substantially" as a benefit?

Impact depends on appeal: Consider whether e-cigarettes are reaching a section of the smoking population that would not otherwise try to quit, even if the quit rate is lower than for example, in Stop Smoking Clinics.

Description of "dual use": High levels of "dual use" (both smoking and vaping) are not problematic unless the authors can show the dual users would otherwise have quit (which no one has done so far). It is inevitable that many people will use both, at least for a while, unless there is a "magic bullet" that works instantly for everyone.

However, dual users still benefit, since there would be a likely reduction in toxic exposure and an increased likelihood of them quitting eventually. It is interesting to note that approximately 93% of people quit smoking as dual users − even if the process entails quitting completely, relapsing, trying again and repeating the cycle.[18]

Benefits of cutting down: Studies that measure cutting down without an alternative source of nicotine are unreliable proxies to indicate the impact of cutting down with an alternative source of clean nicotine. In the absence of alternative nicotine, smokers "compensate" by smoking harder and consuming more tobacco to maintain their nicotine dose. There are relatively few studies involving people that have cut down using a replacement source of nicotine.

Insufficient randomised controlled trials: Random controlled trials (RCTs) are often regarded as the "gold standard" of evidence and, in many situations, they are. But RCTs work best for simple interventions − where one thing can be held constant and its impact measured − (like taking a prescription drug or using a certain teaching method).

Because vaping entails multiple complex and dynamic aspects, RCTs are therefore, not a suitable study method. They have limitations in addressing multifaceted aspects such as varying reasons for vaping or smoking e-cigarettes, increased use, revisions to products and changes in users when trying different products.

While RCTs can be designed to address some or all of these THR issues individually, it is difficult to do them all together. Observational surveys, cohort studies, case studies and testimonials all add more value to the evidence base.

FLAVOURS AND E-CIGARETTE MARKETING AIMED AT CHILDREN

Assuming the obvious: Ask whether the authors have just assumed and asserted that a product with possibly childish characteristics (e.g. using "bubblegum" as a flavour name), will appeal to adolescents and that the manufacturers have done this deliberately with that intention. Check whether there is any data to support the claim.

Has a preference for a flavour been misrepresented as a cause of vaping? Once someone decides to vape, they need to choose a flavour since almost all vaping products are flavoured with something. However, it does not mean this preference caused them to vape to start with.

Benefits of an appealing flavour: If vaping primarily appeals to young smokers, could a flavour or flavour descriptor persuade them to switch from smoking combustible cigarettes to less harmful vaping products?

Are adolescents really trying to emphasise their childishness? Have the authors shown that the availability of flavour caused e-cigarette use that would not otherwise have happened? One needs to consider that adolescents may prefer to emulate adult behaviours.

Age misinterpretation: Is there a misinterpretation of product marketing that is aimed at 25-30 year old smokers or at adults inclined towards feelings of retro, irony or nostalgia?

True purpose of e-cigarette advertising: Consider whether e-cigarette marketing is actually a form of anti-smoking advertising and is therefore potentially beneficial.

UNCERTAINTY AND APPEAL SURROUNDING THE "PRECAUTIONARY APPROACH"

Understanding what is known: When researchers or activists say, "we don't know enough", have they read the main evidence reviews? Do they know what is known and can they summarise that? Statements like these could reveal an unwillingness to engage with, or accept what we do know.

Expert knowledge: Is someone who does not know much actually an expert? Consider whether it would be more useful to consult better experts instead of people that claim not to know much or anything.

Asking the impossible: It is unattainable to travel many years into the future and measure health effects of vaping several decades from now. Therefore, it is disingenuous and unfeasible to demand such knowledge about any new product. We should use the existing information at hand to make the best judgments of risks (e.g. data on chemistry of vapour, short-term health impacts) and set these against the certain knowledge available about smoking.

Uncertainty is a fact: It is fair to state that all policy-making involves making good judgements in the face of uncertainty based on what is known, rather than being paralysed by what is not known.

The precautionary principle makes no sense in this context: It is unwise to trust anyone that adopts the precautionary approach to justify the onerous regulation of THR products based on incomplete evidence. Prohibiting these products, obstructing access to them or applying undue caution on a "precautionary basis" could possibly deny smokers of significant health benefits.

HAS A CONFIDENT POLICY RECOMMENDATION BEEN MADE IN A PAPER THAT PRESENTS DATA?

Going beyond research: Ask whether the authors have made unqualified policy recommendations that are unsupported by their findings. Researchers and some journals commonly assume that publishing a data paper is a licence to make policy recommendations, even though policy was not the subject of the paper.

Following policy-making disciplines: Very few study papers do enough work to justify a policy recommendation. With scientific input being only one element of policymaking, assess whether the authors have drawn up an impact assessment and made an economic appraisal in making policy recommendations.

Have they assessed unintended consequences and incorporated distributional, ethical and legal considerations? Establish whether they have a principled approach to the use of the law, restriction of liberty and justifying public spending.

Bias in policy positions: Question whether the policy positions the authors have taken reveal "investigator bias" – an undisclosed agenda to progress certain policy measures. Policy biases may cast doubt on the objectivity of the work.

Ignoring unintended consequences: Question whether authors have been rigorous in considering unintended consequences. Authors often overlook unintended consequences that may arise from their policy ideas. Some examples of these are:

- Banning e-cigarette advertising that may "hide" alternative to smoking or make these options seem less attractive;
- Big bold warnings on e-cigarettes that might cause smokers to believe they are more dangerous than they are;
- Banning flavours that might reduce the appeal to certain adults and cause relapse to smoking; and
- Banning vaping in all public places, which might cause people not to switch and then relapse.

Uncertainty is a fact:
It is fair to state that all policy-making involves making good judgements in the face of uncertainty based on what is known, rather than being paralysed by what is not known.

Photo by Ave Calvar on Unsplash

SCIENTIFIC ENGAGEMENT AND A "WHOLE-OF-SOCIETY" APPROACH

The United Nations has called for an approach that encompasses terms like "whole-of-society", "whole-of-government", "multi-sector action" and "multi-stakeholder" to prevent and control tobacco-related non-communicable diseases.

Although governments play a key role in tobacco control, they cannot end smoking single-handedly.

Reasonable, proportionate regulation coupled with consumer demand and innovative products can realise the potential of tobacco harm reduction. Conversations between stakeholders – in particular, scientific stakeholder engagement – are needed to produce this win-win scenario.

The absence of industry science remains the key thorny issue surrounding scientific engagement. Whereas some of the most competent scientists and science are now in the industry, Article 5.3 of the FCTC prevents scientific discourse.[4]

For example, the STOP Global Tobacco Industry Interference Index report[19] states: "Article 5.3 is regarded as the backbone of the convention and its importance cannot be over-emphasised;" and "[the] tobacco industry must be denormalized".

Simply put, the science of tobacco and nicotine is complex and cannot be resolved without all stakeholders at the table.

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CHAPTER 8

Barriers to Tobacco Harm Reduction

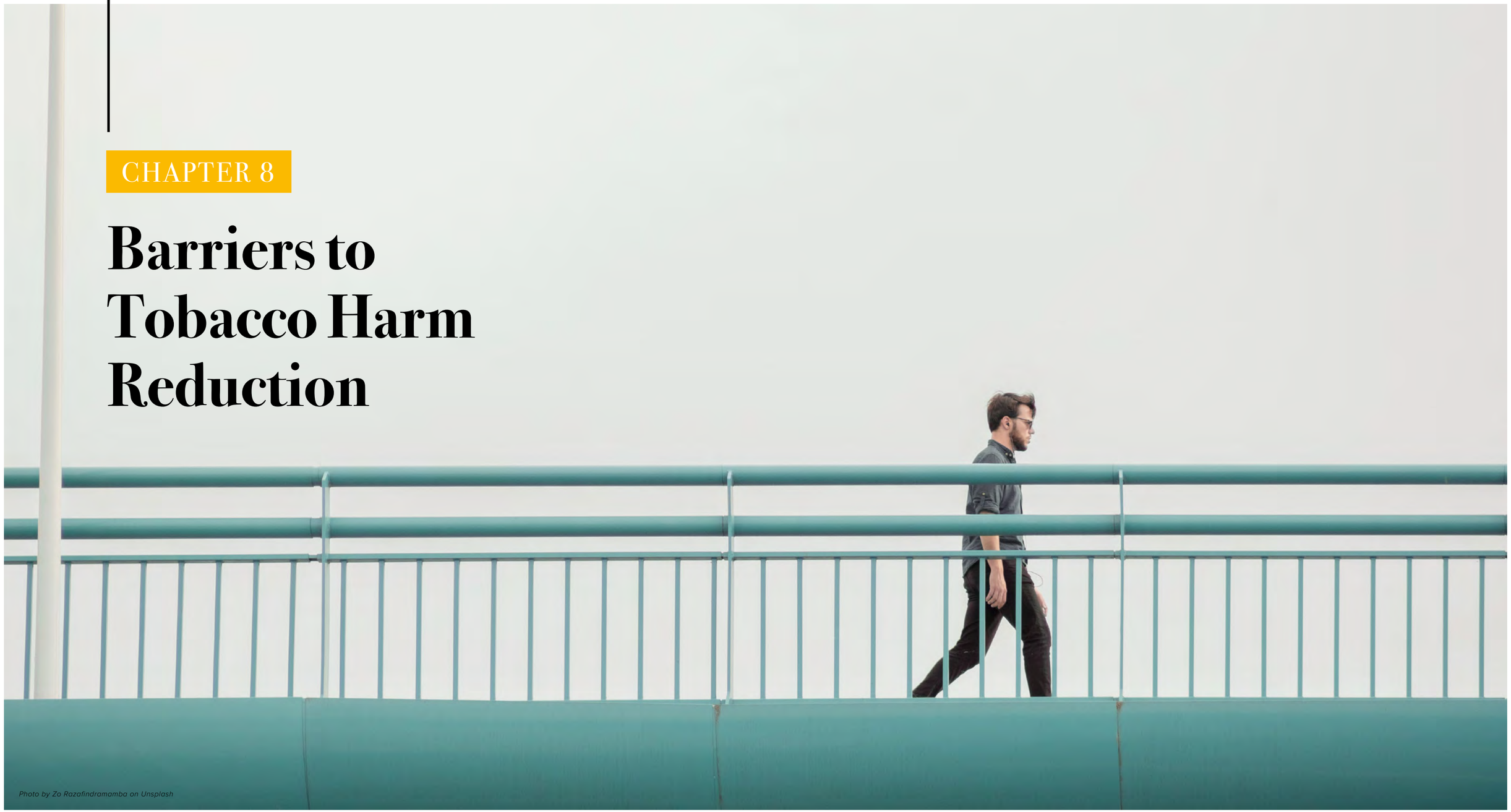

Photo by Zo Razafindramamba on Unsplash

WHY THE OPPOSITION TO TOBACCO HARM REDUCTION (THR)?

With tobacco harm reduction's potential of preventing tobacco-related disease and premature death, it is possible for THR apologists to make the mistake of wanting to be understood, before they make the effort to understand the criticism against THR. It is important to understand the two main arguments of THR critics:

- Risks to users and bystanders arising from exposure to vapour; and
- Population risks arising from changes in smoking or nicotine-using behaviour because of e-cigarettes.

Unfortunately, these arguments can lead to unintended consequences, with media sensationalism as well as draconic regulation and bans leading the way. Ultimately, though, it is the effect on the adult smoker that is most damaging. Instead of quitting or switching to less harmful THR products, they continue smoking the most harmful product – cigarettes. With all the mixed messages and the inability of global public health leaders to communicate risk more precisely, who can blame them?

RISKS ARISING FROM EXPOSURE TO VAPOUR

No one should claim that vaping is entirely benign. It may prove to be, but that cannot be established without many years of data. However, vaping does not need to be harmless or completely safe to make deep inroads into the risks of disease if people switch from smoking.

Studies of liquids and vapour chemistry reveal traces of contaminants and thermal breakdown products that are potentially harmful. Nevertheless, these are at levels generally two orders of magnitude lower than in cigarette smoke and are therefore, unlikely to pose a material threat. Critics of e-cigarettes routinely cite studies suggesting the presence of harmful substances, but risk is determined by exposure, not merely by the presence of a hazardous substance. Moreover, to be clear, low levels of hazardous substances are present in almost everything we consume. The most comprehensive literature review so far concluded[1]:

> ***Current state of knowledge about chemistry of liquids and aerosols associated with electronic cigarettes indicates that there is no evidence that vaping produces inhalable exposures to contaminants of the aerosol that would warrant health concerns by the standards that are used to ensure safety of workplaces. Exposures of bystanders are likely to be orders of magnitude less, and thus pose no apparent concern.***

Some commentators highlight the following issues to make the case that e-cigarettes are harmful.

Nicotine

The active drug in tobacco is not the primary cause of harm in smoking and would not be in vaping. It has been understood for four decades that *"people smoke for the nicotine but die from the tar."*[2] Nicotine is not a cause of cancer, cardiovascular disease or the respiratory conditions that dominate the ill health from smoking.[3]

Furthermore, pure nicotine is not completely benign, but it is widely sold in medicinal form and does not cause any serious illness.[4] The US Surgeon General has made a detailed assessment of nicotine risks[5], and although it is possible to measure many effects on the body, these are trivial compared to smoking: for health, it is *always* better to vape than to smoke.

Nicotine poisoning

There have been a small number of incidents of people or pets swallowing nicotine liquids and some have tried to characterise this risk by reference to the number of calls to poison centres. However, recent analysis shows nicotine toxicity is perhaps 20 times lower than widely assumed.[6] Although calls to US poisons centres are rising in line with growth and public awareness of e-cigarettes and liquids, they represent a tiny fraction of the calls arising from medicines, cosmetics, domestic cleaning products etc.[7][8] There is a simple protective measure available – to insist on child resistant packaging, for which there is an ISO standard.[9]

Ultrafine particles

Some have claimed that the aerosol droplets in e-cigarette vapour have a similar effect on the body as the particles in tobacco smoke or diesel exhaust.[10] This makes little sense as the chemistry of the vapour particle is completely different, and it is the toxicity of the particles that causes damage with tobacco smoke and environmental pollution. Therefore, the entire argument is baseless.[11]

Formaldehyde

A news story originating in Japan suggested that e-cigarette vapour could contain up to ten times as much formaldehyde as conventional cigarette smoke. In fact, this irregular, single result was neither published nor verified.

The device running hot and dry almost certainly caused it. Studying the published results more thoroughly, the overall picture showed formaldehyde levels 6-50 times lower than for cigarettes.[12] The error was repeated in a letter in the New England Journal of Medicine.[13]

It claimed that formaldehyde-related cancer risks from e-cigarettes were 5-15 times higher than for cigarettes, but the experiment made the elementary mistake of running the vaporiser in *"dry puff"* conditions to which no human user would ever be exposed to.[14] *No formaldehyde was detected under normal operating conditions.*

It is important to add that cigarettes contain thousands of chemicals not present in e-cigarettes, while formaldehyde is widely present in the environment It is also present in household products such as glues and preservatives used in some medicines, cosmetics and other consumer products such as dishwashing liquids and fabric softeners.

Carcinogens and toxicants

Carcinogens are found almost everywhere. For example, writing in 1998, one of the leaders in the field said[15]: *"Over 1000 chemicals have been described in coffee: 27 have been tested and 19 are rodent carcinogens. Plants that we eat contain thousands of natural pesticides, which protect plants from insects and other predators: 64 have been tested and 35 are rodent carcinogens."*

The question is whether any carcinogens cause exposures at levels and via pathways that pose a material risk. Where toxicants are found in e-cigarette vapour, they are found at much lower levels than tobacco smoke. The biggest study on toxicants in vapour[16] concluded: *"The levels of the toxicants were 9-450 times lower than in cigarette smoke and were, in many cases, comparable with trace amounts found in the reference product."*

Many of the more important toxins in cigarette smoke are simply not present at all in measurable quantities in vapour. The data on toxicity and carcinogenicity are consistent with the claim that vaping is significantly safer than smoking.

Heavy metals

Traces of metals can be found in some e-cigarette vapour, but at very low levels that do not pose a material risk – namely, equivalent to, or lower than, levels found and permitted in medicines[4]: *"An average user would be exposed to 4-40 times lower amounts for most metals than the maximum daily dose allowance from impurities in medicinal products."* Regulations to cover the materials used in device construction would reduce this still further

Lung irritation

A February 2015 study[17] exposed mice to e-cigarette vapour and concluded, *"E-cig exposure elicits impaired pulmonary anti-microbial defences"* (in mice). In fact, the study greatly over-interpreted the applicability of a mouse study to humans[18], failed to measure impacts for tobacco smoke for comparative purposes and failed to note that free radical exposure was 150 times lower than is typically found for smoking.[19]

RISKS TO THE POPULATION

As it becomes clearer that e-cigarettes offer smokers a significant reduction in risk, the critics of e-cigarettes have moved their focus onto "population" arguments.
This point of view states that although vaping is far less hazardous than smoking for an *individual*, it could be more dangerous at *population* level because it somehow causes changes in the way people smoke. For example:

- By visible displays of smoking-like behaviour or marketing it might "renormalise" smoking;
- Vaping might divert people from quitting smoking because they don't experience the discomfort of temporary withdrawal or feel under so much social pressure; and
- Vaping could be a "gateway"' to smoking for adolescents, and "kiddie flavours" may be used to lure children into nicotine addiction and ultimately towards smoking.

There is no basis to believe any of these effects are real rather than tactical campaign arguments.

Renormalising smoking

The UK's foremost experts in smoking cessation – who also manage the surveillance of the market in nicotine products in England – concluded[20]:

> ***Evidence conflicts with the view that electronic cigarettes are undermining tobacco control or "renormalising" smoking, and they may be contributing to a reduction in smoking prevalence through increased success at quitting smoking.***

The more plausible and obvious hypothesis is that e-cigarettes will function as an alternative to smoking; a gateway exit from smoking and will normalise safer alternatives to smoking.

Marketing that looks like cigarette marketing: There have been some objections that some e-cigarette advertising resembles that used for cigarette advertising.[21][22]

In fact, it is not surprising or undesirable that some advertising is similar in appearance. That is because advertisers are appealing to smokers to switch their smoking behaviour to an alternative to smoking that is significantly less harmful.

If such similar branding enhances the effectiveness of the appeal to smokers, then it is contributing to better health. Note that the use of tobacco brands in e-cigarette marketing ("brand stretching") is illegal in Europe and in most jurisdictions where tobacco advertising is banned – so the only visible brands are rivals to cigarettes.

A code recently published in the UK controls e-cigarette advertising in much the same way as alcohol advertising is controlled. This is a proportionate approach[23][24], which contrasts favourably with the near-complete ban that the European Union (EU) might impose in the future.

Reduced quitting

Where smoking cessation has been studied properly and the results interpreted correctly, there is no indication that e-cigarettes reduce quitting, and nor would a neutral observer expect one.[25] The most thorough survey in the world, the Smoking Toolkit Survey for England[20], concluded in January 2015 that *"Rates of quitting smoking are higher than in previous years. E-cigarettes may have helped approximately 20 000 smokers to stop last year who would not have stopped otherwise."*

Gateway effects

Many activists and some public officials have pointed to rising e-cigarette use among adolescents and suggested they pose a "gateway" risk: namely, that it will lead to more smoking. *There is no evidence supporting this hypothesis anywhere.*

In fact, e-cigarettes appeal primarily to existing smokers. Moreover, the "value proposition" they offer is strongest among existing smokers with growing concern about their health and other costs. Data confirms this expectation, for example, the UK Office for National Statistics states[26]:

> ***E-cigarettes are used almost exclusively by smokers and ex-smokers. Almost none of those who had never smoked cigarettes were e-cigarette users.***

However, this has not stopped wild misinterpretations of data. For example, in the United States in 2013, the National Youth Tobacco Survey Data results showing a rise in e-cigarette use generated extensive media coverage.[27] According to a top public health official:

> ***This raises concern that there may be young people for whom e-cigarettes could be an entry point to use of conventional tobacco products, including cigarettes.***

In fact, the data in this study did not support a gateway effect and a rise in e-cigarette use among adolescents would be expected to mirror the rise in use among adults. In reality, US teenage smoking prevalence fell sharply as e-cigarette use increased and e-cigarette use was highly concentrated among existing smokers.[28]

Figure 1 below indicates the relevant CDC data.

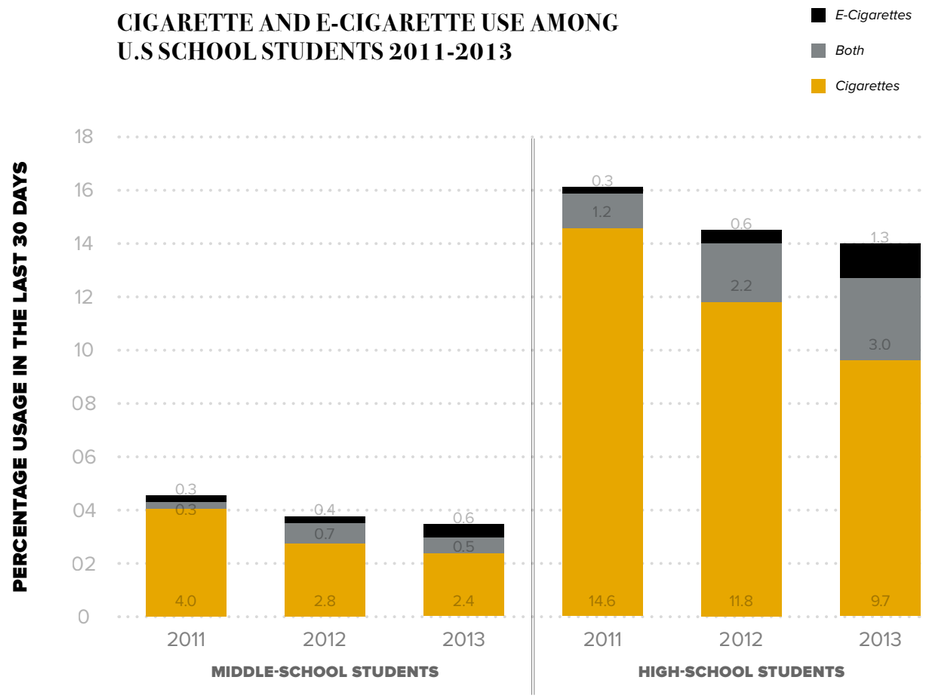

Figure 1: Cigarette and E-cigarette use among US school students (2011-2013)[29]
Source: raw data from CDC National Youth Tobacco Surveys (NYTS). Data analysis and graphic by Brad Rodu

Similar effects were found in France and were confirmed for the United States in the Monitoring the Future[30] survey. While this showed a rise in e-cigarette use, it also found record low rates and record annual declines for "daily" and "past-30-day" cigarette smoking by teens from 2013 to 2014.[31] In essence, we are seeing an increase in e-cigarette use in line with growth in adults, but a sharp decline in cigarette smoking. These are reasons to be positive, not to simply lay the blame at the door of e-cigarettes as a problem.

Understanding and defining gateway effects

It is difficult to find proponents of the gateway effect that can rigorously define what they mean and how they would measure this phenomenon. To establish a gateway effect is difficult in practice. It is necessary to show that a period of e-cigarette use is the reason why someone develops a consolidated smoking habit. It is not sufficient to show that rising e-cigarette use coincided with rising smoking[32], as there could be independent reasons for these trends or a common factor driving them.

Nor is it sufficient to show that a person used e-cigarettes first and then took up smoking – in the absence of e-cigarettes, they may have simply started to smoke anyway. Another noteworthy possibility is that e-cigarette use in adolescents actually plays a protective role, by preventing or diverting the onset of a consolidated cigarette smoking habit. Some care is required in drawing causal conclusions from observational data on e-cigarette use; however, every claim made about detecting a gateway effect fails to address these issues.

Kiddie flavours to appeal to children

It is often asserted, as if it is obvious, that flavours with "childish" characteristics will appeal to adolescents. There is no evidence for this, just assertion. It is actually counter-intuitive since most adolescents are imitating adult behaviour, not reinforcing their status as children. The one study that has looked at the preferences of young people for e-cigarette flavours found extremely low interest (See Figure 2 below).

Teenagers were asked to rate their interest on a scale of 0-10 in using e-cigarettes and were offered a list of flavours. They reported minimal interest (average =0.41 out of 10) – much less than adult smokers (1.73 out of 10) – and their interest did not vary much across flavours.[33] To the extent that teens revealed any preferences, the two flavours that came out top were "Single Malt Scotch" and "Classic Tobacco".

Other studies confirm that adults are attracted to supposedly juvenile flavours like cherry crush or fruit loop. For example, a survey of users of the world's largest e-cigarette user forum (E-Cigarette Forum https://www.e-cigarette-forum.com/) found fruit to be the most popular flavour category.[34] A similar flavour survey of over 4 519 users found 44% used tobacco, 32% menthol/mint, 61% sweet, 15% nuts, 69% fruit, 37% drink and 22% other.[35] Non-users should understand that flavours are an important aspect of vaping and integral to the experience. They are also part of migrating away from tobacco. Initial switchers tend to favour tobacco flavours but gradually move on to non-tobacco flavours, often as part of a permanent switch from smoking.

Perpetuating an addiction – "Nicotine is nicotine is nicotine"

Within the public health community, a well-established group of "abstinence-only" advocates view any type of tobacco use as unacceptable. For them, this would perpetuate an addiction, which in itself is a disease. At times, their views seem almost absolutist and bordering on the unrealisable. Predictably, they apportion most of the blame for the tobacco epidemic to nicotine. They would add that most of the societies who have fully implemented tobacco control measures have seen a decline in smoking prevalence.

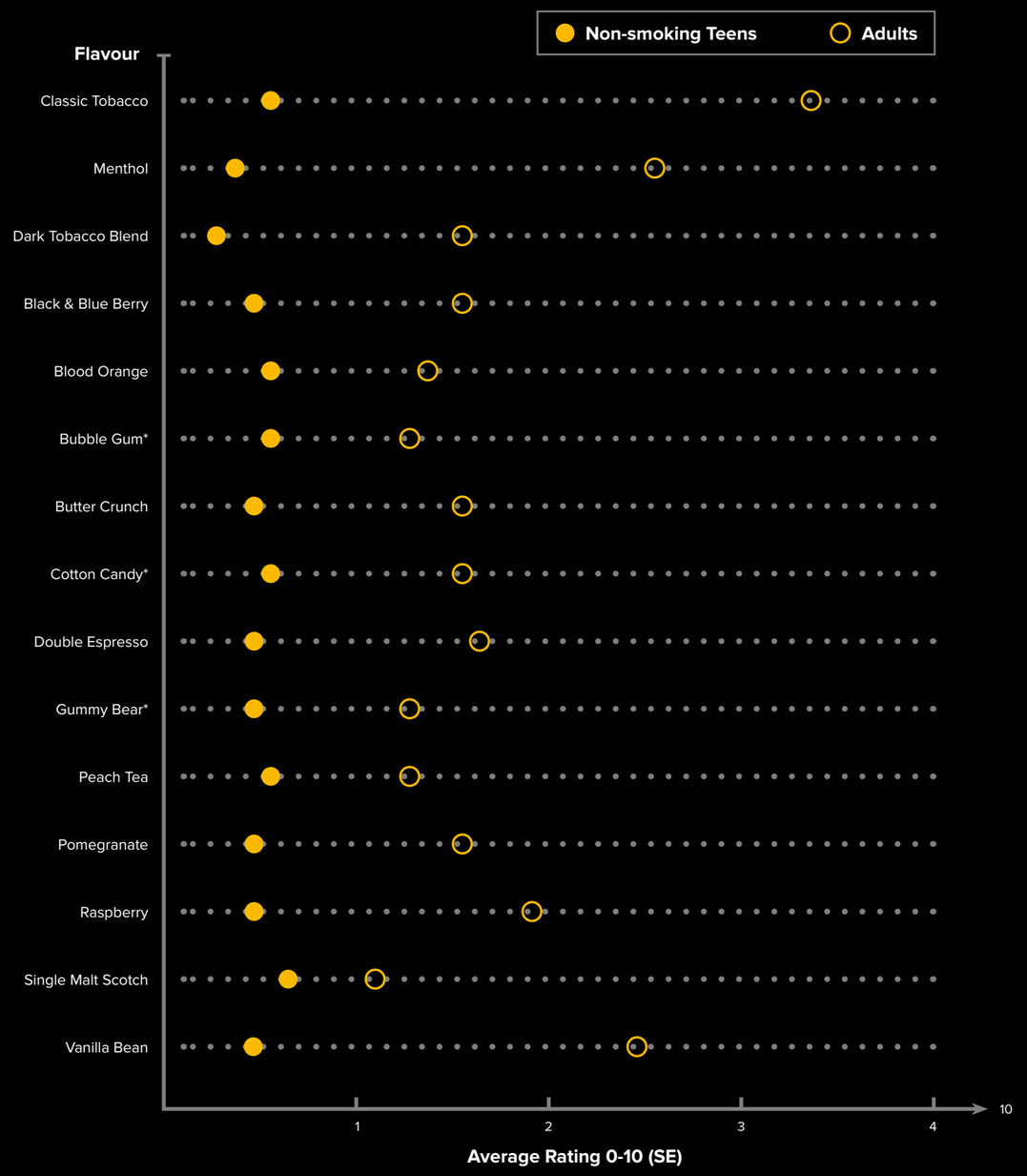

Figure 2: E-Cigarette flavour preference study comparison between non-smoking teens and adult smokers

Photo by John Towner on Unsplash

SEEING THROUGH CONTROVERSY

Many arguments are made against e-cigarettes but almost without exception, they all contain flaws and can mislead users about risks. Writing in an editorial in the journal Addiction[36], Professor Robert West detailed six typical flaws (or "tactics" for those who believe this action is deliberate).

It is worth highlighting the ways in which science is being misused so that readers can be better placed to evaluate the messages.

Failure to quantify: e.g., statement that e-cigarette vapour contains toxins so creating the impression that they are dangerous as cigarettes, without indicating that the concentrations are typically orders of magnitude less than tobacco smoke.

Failure to account for confounding and reverse causality: e.g., arguing that use of e-cigarettes reduces chances of stopping because in cross-sectional surveys the prevalence of e-cigarette use is higher in smokers than in recent ex-smokers.

Selective reporting: e.g., focusing on studies that appear to show harmful effects while ignoring those that do not.

Misrepresentation of outcome measures: e.g., claiming that e-cigarette use is prevalent among youth by using data on the proportion who have ever tried and creating the misleading impression that they are all current e-cigarette users.

Double standards in what is accepted as evidence: e.g., uncritically accepting conclusions from observational studies with major limitations when these claim that electronic cigarettes are causing harm, but discounting similar or better-controlled studies when these appear to show the opposite.

Discrediting the source: e.g., arguing that researchers who have received financial support from e-cigarette manufacturers (and even companies that do not manufacture e-cigarettes) are necessarily biased and their results untrustworthy, and presenting themselves as having no conflicts of interest when their professional and moral stance represents a substantial vested interest.

THE CASE OF SNUS – A CAUTIONARY TALE

Many of the same population arguments were made on a precautionary basis in 1992, in the case to ban “oral tobacco” throughout the EU, despite it being 95-100% less hazardous than smoking.

On accession, Sweden was granted an exemption from the ban. In fact, this form of oral tobacco product known as snus is the reason why Sweden has by far the lowest rate of smoking in the EU: 13% Swedish adults vs 28% EU average.[37] Snus has three main effects in Sweden and Norway: it is used to quit smoking; it is used to substitute smoking; and it diverts young people from onset of smoking. It provides a compelling “proof of concept” for tobacco harm reduction, and a warning about perverse impacts of regulation. It also showed that tobacco control activists were prepared to mount a campaign against a product that has achieved real reductions in disease and premature death.

CONCERN ABOUT THE TOBACCO INDUSTRY

A further source of critics’ concern is the possible negative role of the tobacco industry, which is unsurprising given its history. Currently, it is hard to see what this role could be in practice if the e-cigarette industry remains competitive. E-cigarettes threaten the tobacco industry’s long-standing cigarette-based business model. To survive the disruption, the industry will need to enter the market (as they are already doing), and produce high quality, attractive alternatives to smoking or risk losing share in the recreational nicotine market to other tobacco or non-tobacco e-cigarette companies. They are more likely to become important drivers of a wholesale switch from smoking to vaping through the mechanism of market-based competition.

The real danger from tobacco companies arises from excessively burdensome regulation. This could eliminate competition from more agile or innovative competitors, leaving tobacco companies with an oligopoly protected by regulatory barriers to entry. Paradoxically, it would be endorsed by health organisations. Unfortunately, many public heath establishment organisations and individuals are doing their utmost to cause this to happen. The problem though, is that they do not always realise protecting tobacco companies from competition will be the effect, if not their aim.[38][39]

Photo by Roman Kraft on Unsplash

DISRUPTIVE TECHNOLOGY ALSO CHALLENGES PUBLIC HEALTH

E-cigarettes have empowered smokers to take control of their risks and in the UK, for example they have greatly enhanced the welfare of hundreds of thousands of citizens.

Therefore, e-cigarettes not only challenged the tobacco industry, but also interests in the public sector and civil society, have played no role – or a hostile role – in their growing popularity. Many smokers and vapers are highly perplexed by the hostility of the public health establishment to vaping or tobacco harm reduction. Here are several possible explanations:

- ***Not invented here:*** the products and harm reduction benefits have emerged through free play of producers and consumers in a lightly regulated market. No one in public health has given their approval or been asked for it, no public spending is required and public health organisations have no controlling influence.
- ***Hostility to the private sector:*** culturally, the public health establishment is inclined to paternalism, and state-based or not-for-profit interventions. It instinctively distrusts the private sector and capitalism, and is ill at ease with the idea of consumers as empowered agents.
- ***Countercultural:*** the toolkit of tobacco control is replete with coercive measures: restrictions penalties, (regressive) taxes, fear-based campaigns, medicalisation of smoking and so on. Harm reduction approaches are non-judgemental as they "meet people where they are" and allow them to judge their own interests and preferences.
- ***Undeclared motives:*** some in tobacco control have a "non-smokers" rights' orientation, rather than "population health" orientation, and these have different implicit objectives. As with any issue that involves a recreational drug, there are many role players involved – these include prohibitionists, affronted authority figures ("doctor knows best") and those with concerns about bodily purity.[40]
- ***Conflicts of interest:*** public health academia, science and advocacy are beset by various issues including ideological biases, prior positions to defend, funders' interests to respect, charities' declared policy positions and pharmaceutical funding. Many of these individuals and organisations are highly prone to insularity and a group-think mindset.
- ***Tobacco industry focus:*** many activists and academics have defined their fight as being with the tobacco industry. They also assume what is harmful to them is beneficial to health. This leads to lethargic, muddled thinking in the area of tobacco harm reduction.

Not all individuals or organisations involved exhibit all or any of these characteristics. Yet it is pertinent to outline them here to emphasise the perils of assuming that anyone in a public health profession or that remits to protect health is actually acting rationally in the interests of health.

GETTING KEY CRITICS / OPINION LEADERS ON BOARD – THE HEALTH PROFESSIONALS

Tobacco control provided the insight that health professionals and in particular, medical doctors have tremendous influence in consumer choices. They can play a highly influential role in curbing tobacco use in any community. In fact, during the early part of the last century, doctors were the first to start smoking, but also the first social grouping to quit smoking. This was mostly due to the research of Dr Richard Doll, whose 1950 article[41] in the British Medical Journal (BMJ) essentially started the tobacco control movement. In this article, he powerfully established the link between cigarette smoking in medical doctors and lung cancer.

Likewise, it is clear that where medical doctors take the lead and stop smoking themselves, advise patients to quit and advocate for policy change, sustained action follows.
Dr Derek Yach, former Executive Director at the WHO, states that[42] *"physicians were, in fact, key to progress in the USA and OECD countries, where smoking rates have dropped steadily over the decades. In these countries, doctors' smoking rates dropped and, within a decade, smoking rates fell in the general population. In many major LMICs, physician smoking rates remain extremely high. Correspondingly, doctors' voices and advocacy are weak. Until this changes, progress will be slow."*

It is clear that future physicians and health leaders will depend on this generation to have made wise judgments and offered the right advice to the right patients at the right time. For the practicing physician today, the evidence is clear – build tobacco harm reduction into your practice without delay!

CONSEQUENCES OF THE OPPOSITION TO THR

The opposition of THR products has had real, impactful consequences worldwide, which has limited its potential to prevent tobacco-related disease and death.

WIDESPREAD BANS

E-cigarettes are banned altogether in 30 countries, while seven countries have banned nicotine-containing E-cigarettes.[43] Heated tobacco products are banned in six countries[44], while snus is banned in Australia, New Zealand and the countries of the European Union (except Sweden). Predictably, these bans have led to a flourishing illicit trade in such products, for example, those containing e-liquid in Australia.[45]

TAXES

Taxes have a significant impact on consumer behaviour. In fact, they have consistently proven to be one of the most effective public health tools to stop smoking. If high taxes are placed on THR products, consumers are less likely to switch to them, and might continue using cigarettes, the most harmful products. Up to 2020, 14 countries have placed taxes on e-cigarettes.[43][44]

More worryingly, the National Bureau of Economic Research[46] in the USA did a study to determine whether high taxes on E-cigarettes had deterred smokers from quitting. Their unequivocal conclusion was that higher e-cig taxes increased adult smoking rates and reduced quitting.

MEDIA SENSATIONALISM

The most disturbing example of “fake news” or gross media misrepresentation was the outbreak of acute, severe cases of lung injury and deaths in the US in late 2019. For several months, E-cigarettes (vaping products) were blamed in the media as the cause of the “e-cigarette or vaping product use associated lung injury (EVALI)”. This fake storyline was maintained for months, and baseless media reports circulated in numerous newspapers, TV and radio stories.[47]

Although the real cause of the outbreak was the use of vitamin-E acetate – a thickening agent in illegal/black market tetrahydrocannabinol (THC) liquids consumed with vapourisers – the facts were not publicised with the same rigour as the false story.

To be clear, not all individuals or organisations involved in public health exhibit all or any of these views, but unfortunately the net effect at this time, is that tobacco harm reduction products are mostly viewed in a negative light.

It is imperative that sound science, responsible risk communication and proportionate regulation of THR products are established without delay. This way the main goal can be achieved - preventing tobacco-related disease and premature death.

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CHAPTER 9

Tobacco Harm Reduction is an Ethical Choice

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The tobacco control debate has largely ignored the ethical elements of harm reduction. Many tobacco-related health problems involve multifaceted ethical dilemmas, with no easy answers. Physicians and health professionals are often unprepared to manage these competently when considering tobacco control and tobacco harm reduction. This chapter focuses on informing and strengthening the ethical mindset and consequential practice of physicians and health professionals as they consider tobacco control and tobacco harm reduction.

Public health and policies essentially govern tobacco control. It tends to emphasise health promotion and seeks to find long-term solutions for societal health problems. The interaction between physician and patient is rather different. Few patients expect their physicians to save the world. They want them to focus on their specific health problems and offer a cure… instantly, if possible!

Therefore, we could argue that tobacco control is a natural product of a population-based, public health mindset. Tobacco harm reduction, however, seems to be a normal outflow of health care provision to the individual. Therefore, primary care health professionals should find it much easier to evaluate the potential role of a principled and pragmatic harm reduction approach in the management of tobacco use.

Until now, most stakeholders have unfortunately mainly ignored the ethical aspects of tobacco use. This includes physicians, who claim ethics as one of the pillars of the medical profession. It was Hippocrates who famously referred to a basic pillar of medical ethics and the relationship between physician and patient: ***"First, do no harm."***

With his wisdom in mind, have we considered the ethical implications of current approaches in tobacco control? There is ample evidence that tobacco control has been beneficial to public health and society in general. Nevertheless, could we argue that it has actually caused some harm to certain individuals seeking a cure for their smoking addiction? Yes, posing this question is almost sacrilege, yet that is the essence of ethics: evaluating what is moral and right.

As a member of the tobacco control community, I recall how many of the phrases we coined reflected a stark black-and-white world, to illustrate our view of tobacco. We named our global tobacco control conferences "Tobacco or Health".

Our grim advice to smokers was to "quit or die". We dealt only in absolutist terms when advocating for a tobacco-free world. The only possibilities were "either… or", with no thought of a "both… and" solution. We did all these things to maximise the societal impact of tobacco control.

Now is the time for health professionals to enter into a considered debate about the ethics of harm reduction in tobacco, and specifically, to reflect on the human rights of the individuals involved. Physicians, in particular, can play a meaningful role in this debate since the core of their work is the patient-physician relationship.

This unique relationship facilitates an exchange of scientific knowledge and care within a framework of ethics and trust. It also places the individual patient, as opposed to all of society, at the centre of the question – what is in the best interests of the patient in front of me?

Consider for a moment a consultation between Ms A, a 60-cigarette-per-day smoker, who visits a general practitioner, Dr B. The patient has chronic pulmonary obstructive disease caused by her long-term smoking, is continually short of breath and suffers from recurrent upper respiratory tract infections. She has tried to quit smoking at least ten times. This has included trying some of the evidence-based cessation programmes that Dr B has prescribed. Ms A has also experimented with herbal medicine, homeopathy and acupuncture, which failed like all the other methods.

She refers to her cigarette brand as if it were a close friend, from whom she could not even bear parting. She is really at her wit's end. Ms A is beginning to contemplate suicide, because, as she puts it: "I can't see the point of living. I don't have any breath left in my body." She is desperate for help.

If Dr B were practicing in Australia and followed current "best practice", he would have told Ms A that quitting is the only option. He would have prescribed a short course of nicotine replacement therapy and perhaps some behavioural support. With some tobacco control experts in Australia advocating unassisted quitting, he might even advise her to go "cold turkey"!

In Sweden or Norway, Dr B's advice might have been quite different. In these countries, it is accepted cultural and medical practice to advise patients to quit, but if they can't, to switch to an alternative such as snus.

Dr B would tell Ms A: "If you switch to snus, even of the same brand as the cigarettes you are so attached to, you will minimise the harm caused by the smoked tobacco. While snus is not harmless, it is at least 95% less harmful than the cigarettes you are smoking. Why don't you use e-cigarettes or snus as a way to step down from cigarettes?"

This anecdote is actually a very realistic portrayal of what happens between physicians and patients, and such an interaction deserves serious ethical reflection. Was the Swedish Dr B acting in an unethical manner by advising Ms A to simply switch to another form of tobacco? (He knew his advice would perpetuate her nicotine addiction, even though it would reduce the bodily harm). On the other hand, did the Australian Dr B act unethically by refusing to offer his patient any advice other than quitting?

This raises questions about physician behaviour and decision-making – not scientific or technical questions, such as how to treat asthma or perform an appendectomy – but questions about values, rights and responsibilities. For physicians, these questions are just as important as the scientific and technical ones.

DEFINING ETHICS

So, what exactly is ethics and how does it help physicians and health professionals deal with such questions? In simple terms, ethics is the study of morality – of what is right and wrong. It involves carefully and systematically reflecting on and analysing moral decisions and behaviour, whether past, present or future. Applied to tobacco harm reduction, ethical analysis provides some valuable insights.

VALUES IN MEDICAL ETHICS

Understanding the values of the medical profession is an important foundation for all physicians in training. It is for this reason that medical schools include medical ethics courses in their curriculum and the World Medical Association (www.wma.net), the global representative body for physicians, not only publishes the Medical Ethics Manual but also offers an online course in medical ethics.[1][2]

"Ethics is the study of morality – of what is right and wrong."

Medical ethics discussions commonly cite the following six values:

- **Autonomy:** Recognition of the patient's right to self-determination, i.e. the right to refuse or choose their treatment.
- **Beneficence:** Act in a manner that promotes the wellbeing of others. In the medical context, this means taking actions that serve the best interests of patients.
- **Non-malfeasance:** *"First, do no harm."*
- **Justice:** Concerns the distribution of scarce health resources, and the decision of who receives scarce treatments (fairness and equality).
- **Dignity:** The patients (and the treating physician) have the right to dignity.
- **Truthfulness and honesty:** The concept of informed consent is a sensitive subject in medicine, especially after the disgraceful behaviour of some physicians who performed horrendous experiments on human subjects during the Second World War and were subsequently tried at the Nuremberg trials.

These values represent a framework of thinking, as opposed to offering clear-cut answers to ethical dilemmas. In using these values to evaluate whether tobacco harm reduction is "ethical" or not, we should apply them within a meaningful context.

We expect physicians to exemplify such values, in addition to displaying compassion, competence and physician autonomy, which are unique to the medical profession.

Physician autonomy refers to the high degree of clinical freedom physicians have had over the centuries to determine the standards of medical education and medical practice. In many countries, physician autonomy has been moderated by governments, managed care systems and other authorities imposing controls on physicians. This, then, raises another key question in the ethics debate – *who decides what is ethical?*

WHO DECIDES WHAT IS ETHICAL?

There is no single answer to this question, because ethics is pluralistic. In traditional societies, there is usually greater agreement on ethics and significant peer pressure to act in one way or the other. Laws sometimes reinforce ethical behaviour.

Culture and religion may also play a role in shaping the definition of what is ethical or not. Less traditional societies might have other ways of deciding what is ethical.

Over the years, some basic human rights have been formulated at a global level. One example is The United Nations Universal Declaration of Human Rights.[3]

Other rights that are important to medicine include the rights to life, to freedom from discrimination, torture and cruelty, inhuman or degrading treatment, to freedom of opinion and expression, to equal access to public services in one's country, and to medical care.

Physicians should consider the question, "Who decides what is ethical?" in the context of the profession's historical process of ethical review, whereby it has developed its own standards. Codes of ethics and position statements often express these standards.

For example, medical, dental, nursing and pharmacy associations each have their own versions of ethical codes and practices.

This privilege of the medical profession – its ability to determine its own ethical codes – is not absolute, however. Physicians have always been subject to the general laws of the country in which they practice.

"**The Health Of My Patient** will be my first consideration."- *The World Medical Association Declaration of Geneva*

WHAT PROCESSES ARE USED TO DECIDE WHAT IS ETHICAL?

There are many subjective ways to decide what you generally consider ethical or not. This includes intuition, emotions, habits followed in society, imitating other role models or conforming to figures of authority. In medical ethics, however, we use more deterministic approaches to make rulings. Four such approaches can be identified:

- **Deontology** entails identifying specific, sound rules that can serve as basis for making moral decisions.
- **Consequentialism** uses an analytical process to determine the likely consequences or outcomes of different choices and actions. Thus, the ethically preferred choice (or right answer) would be the action or series of actions with the best-predicted outcomes. Utilitarianism is one of the best examples of this form of ethical thinking, where we regard 'utility' or 'the greatest good for the greatest number' as the better outcome.
- **Principlism** entails using ethical principles as the basis for making moral decisions.
- **Virtue ethics** emphasises the character traits of individual decision-makers. We expect physicians to have compassion, honesty and dedication and regard those who possess these virtues being able to make sound ethical decisions.

Each of these approaches has its strengths and weaknesses. In most cases, combining all four approaches is recommended as the best way to make ethical decisions. Evaluating tobacco harm reduction within this framework means we should first consider the difference between individual and societal rights.

INDIVIDUAL RIGHTS VS. SOCIETAL RIGHTS

Physicians are not merely involved in relationships with their patients; they also have a 'social contract' with society. This relationship with society provides the physician with definite privileges and access to certain health resources as well as an obligation to use these resources for the benefit of others. In this way, modern medicine has evolved into a more socialised activity. Still, the Hippocratic tradition of medical ethics does not answer every question posed by modern medical practice.

If we were to apply the four principles of Deontology, Consequentialism, Principlism and Virtue ethics to issues related to the scarce resources available for tobacco cessation treatment, how could physicians contribute? Granted, we cannot expect physicians to become experts in the highly complex science of resource allocation in health care systems. Yet, physicians should play their part in increasing access to and providing equity of services and treatments for their patients.

> The World Medical Association Declaration on the Rights of the Patient[4] states:
> ***"Whenever legislation, government action or any other administration or institution denies patients [their] rights, physicians should pursue appropriate means to assure or to restore them. Physicians are also called upon to play a major role in the allocation of society's scarce healthcare resources, and sometimes they have a duty to prevent patients from accessing services to which they are not entitled. Implementing these responsibilities can raise ethical conflicts, especially when the interests of society seem to conflict with those of individual patients."***

It follows that individuals who are thinking of using less hazardous forms of tobacco, have a right to know that there are smokeless products that are safer than cigarettes and that their physicians should tell them. [5][6]

One argument made against tobacco harm reduction is that, although it might benefit the individual smoker, it will *potentially* lead to greater risk for society.

For a large reduction in risk, it is possible or even probable, that the use of smokeless tobacco products would not increase to a level that would cause net societal harm. Snus and medicinal nicotine are so much safer than cigarettes that net societal harm is very unlikely.[7][8][9]

"Snus and medicinal nicotine are so much safer than cigarettes that net societal harm is very unlikely."

PUBLIC HEALTH VS INDIVIDUAL HEALTH

There is sometimes conflict between 'public health' and 'individual health'. This is unfortunate because individuals make up the public or society, and in a perfect world, the best interest of the patient would also be that of the society.

In tobacco harm reduction, a divide is clearly visible. For example, Swedish citizens are allowed (and even advised) to use snus as a cessation or substitute product for combustible tobacco (cigarettes). However, in other EU countries, snus is forbidden, so this is not possible. What advice then should we give physicians who work in several EU regions?

> Here, a sensible guideline is the World Medical Association's Statement on Health Promotion, which notes:
> ***"Medical practitioners and their professional associations have an ethical duty and professional responsibility to act in the best interests of their patients at all times and to integrate this responsibility with a broader concern for and involvement in promoting and assuring the health of the public."***
>
> In applying this principle to tobacco harm reduction, Dr Lynn T Kozlowski of the Department of Biobehavioral Health at Pennsylvania State University offers an unambiguous recommendation on whose rights should prevail:
> ***"Public health concerns should trump individual rights only when there is clear and convincing evidence of harm to society. Lacking that evidence, individual rights should prevail."*** [8][10]

It's clear that ethical decision-making can be challenging. But that does not mean we should ignore the central question in this chapter – "Is tobacco harm reduction ethical?"

THE ETHICAL CONTEXT FOR TOBACCO HARM REDUCTION

In advising smokers to adopt tobacco harm reduction strategies, physicians and health professionals can recommend that they:

- Stop tobacco use altogether, which is always the preferred option;
- Use nicotine replacement therapy as an aid to quitting all forms of tobacco; or
- Use a recognised approach to tobacco harm reduction by switching to safer tobacco products to reduce the harm caused by smoked tobacco.

Health professionals need to consider that cigarettes are still freely available at low prices, while medicinal nicotine products are more expensive. This means that many people are unable to purchase medicinal nicotine for the same price as cigarettes. Moreover, some smokeless tobacco products are prohibited, denying smokers the ability to choose safer nicotine products. Bearing these facts in mind, what are the arguments for and against tobacco harm reduction?

Photo by Christopher Sardegna on Unsplash

ARGUMENTS AGAINST TOBACCO HARM REDUCTION

- The first objection against a harm reduction approach is that smoking is bad and merely substituting one form of tobacco with another perpetuates the use of an addictive substance in society.

- A very sensitive issue for the public health community relates to children. If children were to use low risk nicotine, the most valid and troubling concern is that it might lead to smoking (of cigarettes).

- Harm reduction decreases the effectiveness of the central message of tobacco control, that all nicotine or tobacco product use is or is potentially dangerous and undesirable.

- Thus, if tobacco control efforts are successful, it will not be necessary to allow tobacco harm reduction.

- Promoting harm reduction could create a perception that the tobacco industry can actually play a constructive role in society, while at the same time continuing to sell highly hazardous cigarettes.

- Public health advocates should not promote anything that is not completely healthy.

- Less hazardous nicotine products might prolong smoking of cigarettes, as it acts as a 'temporary crutch' during times when smokers cannot smoke cigarettes.

ARGUMENTS FOR TOBACCO HARM REDUCTION

Autonomy and individual rights

An accepted principle of modern health ethics is that people have a right to make informed choices about their own health. Authorities are therefore, obliged to provide health information that enables individuals to make a reasoned decision. For example, with THR, this would entail highlighting the existence of low risk nicotine products and providing access to relevant information. The *status quo* in tobacco and nicotine medicine denies smokers the right to choose safer nicotine products, as cigarettes are cheap and *"under-regulated"*, while medicinal nicotine products are expensive and available only under regulations that restrict availability and effectiveness. Most countries ban smokeless tobacco, despite good evidence that it can be effective for smoking cessation.

Beneficence/paternalism

Restricting access to smoked tobacco or increasing access to low risk nicotine can be seen as paternalistic. The key question here is, *"Which policy would have the better consequences?"*

Consequentialist perspectives

From a consequentialist standpoint, there is a solid base of evidence that using less hazardous tobacco products reduces the harm to individuals. The main issue here is whether restricting access to smoked tobacco and increasing the availability to low risk nicotine would deliver better health outcomes for society. Other ethical factors to consider are that restricting smoked tobacco might lead to an increase in the illicit trade of substandard cigarettes, while the increase of low risk nicotine products might also result in an increased addiction to an addictive substance.

Justice

It could be argued that restricting only smoked tobacco and not balancing it with increased availability and access to low risk nicotine products, is unfair. Simultaneous action in both these areas would be more just. It is also more likely to produce a better net health benefit than taking action in only one or other area.

CONCLUSIONS

Ethical considerations are an important component of the debate on the advisability of tobacco harm reduction. Clearly, curtailing or even ceasing tobacco use would be the most desirable scenario. If we agree, however, that this is unlikely to happen soon, approaching tobacco harm reduction from an ethical basis seems compelling.

There is an ethical need to alter the tobacco and nicotine ecosystem so that it:

- Discourages those who want to start smoking;
- Makes it easier to quit smoking;
- Improves access to lower risk nicotine products while discouraging their use by non-smokers;
- Facilitates substitution from more to less hazardous tobacco products to improve health outcomes; and
- Develops a regulatory and taxation system that incentivises better health outcomes through marketing, pricing and tax mechanisms.

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CHAPTER 10

Conclusions

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CONCLUSIONS

- Smoking of combustible cigarettes remains the single biggest cause of non-communicable disease and threat to public health.

- Tobacco and nicotine products can be placed on a continuum of harm – from the most harmful of combusted tobacco – to much lower harms of non-combustible nicotine delivery with or without tobacco, including Nicotine Replacement Therapy (NRT).

- For net public health benefit, the trend towards switching from high-risk smoked products such as cigarettes, to low-risk, smoke-free products such as e-cigarettes, heated tobacco products and smokeless tobacco, should be accelerated.

- This approach is known as 'tobacco harm reduction' (THR), and is based on the idea that 'people smoke for the nicotine but die from the tar.' It works because almost all of the disease risk attributable to smoking arises from the smoke, which contains particles of tar and toxic gases that are inhaled from burning.

- Consumers and the public, as part of their basic human rights, must be accurately educated about the relative harms of nicotine- containing products relative to smoking.

- Tobacco control and tobacco harm reduction are falsely regarded as opposites. These two methodologies are in fact complementary, not contradictory.

- This harm reduction concept is endorsed in Article 1 of the World Health Organization Framework Convention on Tobacco Control (FCTC) and is supported by many scientists and policy experts world-wide. It is a complement, not an alternative to established tobacco control approaches. Its success lies in giving smokers additional and more appealing options to quit smoking.

- Therefore, tobacco control strategies should embrace the concept of harm reduction. In addition, regulations, policies, and interventions should be coordinated to facilitate the move of smokers away from cigarettes toward less harmful nicotine delivery products, while preventing the adoption of regular nicotine-containing or tobacco product use among underaged persons (younger than 18 years).

- Nicotine creates dependence, which keeps people smoking. The smoke contains thousands of toxic agents, many of which are formed in reactions during combustion (burning). If smokers can find satisfactory alternatives to cigarettes that do not involve combustion but do provide nicotine, then they would avoid almost all of the disease risk.

- E-cigarette use or 'vaping' has emerged as a popular new technology and phenomenon. The devices deliver nicotine with added flavours via an aerosol (liquid mist). Vaping is popular with many former smokers because it mimics many aspects of smoking, not just nicotine. This includes hand-to-mouth habits and behavioural rituals, while also providing a pleasurable sensory experience and flavours that aid in switching. E-cigarettes are largely marketed as alternatives to smoking as consumer products and are intended to be pleasurable. That is an important difference when compared with nicotine replacement therapy or smoking cessation medicines. The consumer appeal of vaping could be the reason why it may attract smokers in greater numbers and faster than established smoking cessation approaches.

- There is also a new generation of heated tobacco products that heat tobacco instead of burning it. These smoke-free products also feature a flavoured vapour aerosol but they do not cause combustion. In three years following the introduction of heated tobacco products in Japan, cigarettes sales volumes declined by an unprecedented 33%. There has also been renewed interest in smokeless tobacco with the experience of snus, a form of smokeless tobacco that is becoming more widely recognised in Scandinavia. . For example, in Sweden where snus use has been displacing smoking, adult daily smoking prevalence has already fallen to 5% – compared to a European Union average of 26%.

- Like many new and disruptive innovations, there are also potential risks. Many have expressed concerns about abuse, youth uptake and unknown long-term health effects. There is however, a wealth of existing evidence to provide reassurance. Regulators must however, implement effective regulation in an effort to exploit the opportunities these new innovations present, while also mitigating the risks of possible adverse effects.

- Effective regulation involves striking a balance – between measures that are so weak they fail to have the intended effect – and measures that are so excessive that they cause unintended harm. An example of the latter is obstructing smokers switching from smoking to become smoke-free by making smoke-free alternatives more expensive, less appealing or more difficult to access. 'Risk-proportionate regulation' is the appropriate way to strike this balance. adopt. This imposes regulatory burdens and controls in proportion to the risk posed by the product, but also taking account of the opportunities it offers.

- Regulatory frameworks should therefore, maximise population benefit and minimise population harm. For this to occur, all dimensions of nicotine-containing products should be taken into consideration, including their relative harm, appeal to consumers and sufficiently satisfying nicotine delivery.

- Many governments are currently revisiting the most proportionate, risk-based regulatory framework for consumer nicotine products. They have the opportunity to introduce world best practice by developing a framework for risk-proportionate regulation for smoke-free alternative nicotine products.

KEY FEATURES OF SUCH A FRAMEWORK SHOULD INCLUDE THE FOLLOWING:

- **DIFFERENTIATE BETWEEN SMOKED AND SMOKE-FREE PRODUCTS.** A comprehensive framework would cover all forms of consumer nicotine products. The key differentiator for policy purposes is whether the product is for smoking. Combustion is far more important than the distinction between tobacco and non-tobacco products. Smoke-free tobacco and nicotine products can displace smoking and greatly reduce health burdens. It follows that they should be treated differently to smoked products – reflecting opportunity as well as risk.

- **A NUANCED APPROACH TO YOUTH USE OF SMOKE-FREE PRODUCTS.** Measures introduced to protect youth should focus primarily on responsible marketing and not on modifying or limiting the appeal of the product itself to adults. Youth use of smoke-free products may be beneficial for some young people who are smokers or would-be smokers. For this reason, it is important to recognise that measures aimed to "protect" youth could potentially harm some young people.

- **RECOGNISE THAT FLAVOURS PLAY AN IMPORTANT ROLE.** Flavours are integral to the appeal of smoke-free alternatives and an essential part of the proposition to encourage smokers to try switching and remain smoke-free. They also raise concerns about attracting non-smoking youth. We recommend focusing controls on marketing, branding and flavour descriptors rather than on banning particular flavour chemicals or categories (except where there are safety concerns).

- **PLACE CONTROLS ON ADVERTISING, NOT AN OUTRIGHT BAN.** Advertising allows new smoke-free products and innovation to reach smokers and encourage switching. It is, in essence, anti-smoking advertising. Controls on themes, placement, timing and media are appropriate, but not a ban. It is important to recognise that a ban on advertising of smoke-free alternatives results in protecting the dominant cigarette trade and discouraging smoking cessation.

- **THE POLICY FOR USE OF SMOKE-FREE PRODUCTS IN PUBLIC SPACES SHOULD BE A MATTER FOR OWNERS OR MANAGERS.** In the absence of evidence of a plausible material risk to bystanders arising from vaping or heated tobacco products, governments should not mandate wide-ranging bans; nor should they treat smoke-free vapour products as though they are smoked products. The same reasoning applies to limitations that local authorities place on vaping in outdoor places, e.g., central business districts, beaches and parks. The role of governments should be to provide factually correct information to assist decision-making by owners and managers.

- **WARNING AND PACKAGING LABELS SHOULD CONVEY ACCURATE INFORMATION INCLUDING MESSAGES THAT EXPLAIN RELATIVE RISK.** Warnings should not be misused to scare users out of trying products that could be life-saving for them. They should instead, focus on helping smokers make better-informed decisions by communicating relevant risk information, including risks relative to smoking, and ideally using a variety of statements authorised by health officials.

- **SMOKE-FREE PRODUCTS SHOULD HAVE ACCESS TO THE MARKET VIA A NOTIFICATION REGIME.** There should be no requirement for pre-market authorisation, but post-market surveillance and a system for product stewardship that allows improvements and innovations to assist in mitigating safety risks or emerging problems.

- **PRODUCTS SHOULD MEET SPECIFIC SAFETY STANDARDS FOR DEVICES, LIQUIDS AND INGREDIENTS.** Such standards for chemical, thermal, mechanical and electrical safety are emerging internationally. Product standards for novel smoke-free alternatives should provide assurance to regulators and consumers, for example manufacturing and testing criteria to demonstrate and confirm no combustion in heated tobacco products. Established and recommended standards already exist for smokeless tobacco to draw on.

- **PLAIN-PACKAGING SHOULD BE MANDATORY FOR SMOKED PRODUCTS ONLY.** The rationale for standardised plain packaging does not apply to smoke-free alternatives, as they impose both low risks and offer substantial benefits to smokers who switch. Different packaging would also help convey the different risk profile of these products to consumers in a clear and intuitive manner.

- **THE FISCAL REGIME SHOULD CREATE A STRONG INCENTIVE TO SWITCH FROM SMOKING TO SMOKE-FREE PRODUCTS.** Most smoke-free products should attract only standard sales taxes and zero excise duties. If excise duty is applied, it should leave the highest-taxed smoke-free product with a much lower tax burden than the lowest-taxed smoked product to support switching.

- **PUBLIC HEALTH AGENCIES SHOULD PROVIDE WELL-CRAFTED COMMUNICATIONS TO HELP SMOKERS MAKE INFORMED CHOICES.** Public health communicators should engage all relevant stakeholders in communicating risk and the case to switch from smoking to smoke-free products.

- **INVOLVE THE PRIVATE SECTOR AND ITS EXPERIENCE IN DEVELOPING INNOVATIVE PRODUCTS.** The private sector (specifically product manufacturers) need incentives to develop and market reduced-harm products. It is important to emphasise that no false or misleading health claims can be permitted.

- **IMPROVED STAKEHOLDER ENGAGEMENT AND COLLABORATION.** Constructive engagement between all stakeholders will be particularly helpful in THR research, data collection on illicit trade and reduced harm product development and its science.

- **RESPECT THE ETHICAL FRAMEWORK OF THR AND RECOGNISE THE CONSUMER'S FUNDAMENTAL HUMAN RIGHT TO HEALTH.** The ethical imperatives must be respected, especially those related to ensuring the health autonomy of the consumer and facilitating the best consequences in health outcomes. Currently, many smokers are denied the right to choose a safer nicotine product, either because some smokeless tobacco products are banned (e.g. in the EU), or because medicinal nicotine products are prohibitively expensive and often difficult to find.

ADVICE TO PHYSICIANS AND HEALTH PROFESSIONALS

1. Stop smoking yourself. Physicians & health professionals should act as role model of health and healthy choices.
2. Practice workplace wellness. Insist on smoke-free environments in all medical settings.
3. Medical ethics makes you different. Consider your ethical responsibilities.
4. First, do no harm. Failing to tell your patients about ways to reduce harm to their bodies caused by smoking is harmful.
5. Understand the difference between societal and individual rights and interests. Focus on the best interests of your individual patient. This will be best served if you help reduce harm.
6. In addition to the word 'quit', learn and use the word 'SWITCH'.
7. Try to include research as part of your practice, especially.
8. Become fluent in tobacco harm reduction!

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Glossary of Terms

AEROSOL
Cigarette smoke is an aerosol consisting of a cloud of very small (0.01 to 20µm in diameter) particles, vapours and gases.

ALKALOIDS
A name given to a large group of chemicals that typically are found in seed plants and often have physiological effects on humans. Nicotine and caffeine are alkaloids.

BIOMARKERS OF EXPOSURE
Specific biological molecules that can be measured in body fluid (blood, breath, saliva or urine) and that is indicative of how much of a particular substance has been taken into the body (e.g. a toxicant in cigarette smoke). A Biomarker of exposure to nicotine is its metabolite (metabolic breakdown product), cotinine.

BIOMARKER OF POTENTIAL HARM
A specific biological molecule, change or effect produced by the body, that can be measured and that is indicative of the progress of disease. For tobacco harm reduction we are interested in Biomarkers of Harm that can both respond to exposure to cigarette smoke Toxicants and are indicators of smoking-related disease progression.

CARBON MONOXIDE (CO)
A toxic gas formed during incomplete combustion, and by thermal degradation, of organic substances. It is present in smoke and measured both as a volume concentration (%) and total yields (mg/cig).

'CLEARING THE SMOKE'
A publication produced by The Institute of Medicine (IOM) in the U.S.A. in 2001. It assessed the scientific basis for tobacco harm reduction, specifically with respect to Potentially Reduced Exposure Products (PREPs).

COTININE
The major stable human metabolite of nicotine.

DEPENDENCE
The term used by many scientific bodies to describe Addiction. In the case of smoking, 'dependence' refers to the behaviour of smokers who despite knowledge of the risks smoke frequently and would find it hard to stop.

DOSE
The amount of material (smoke toxicant) taken up by the body. In tobacco and nicotine product use studies, dose will be related to the duration of use and product quantity of a smoker's intake of smoke and smoke-toxicants.

DOSE RESPONSE
Describes the relationship between dose of a substance over time and the associated biological response. For cigarette smoking, it means that the greater the dose over time (i.e. numbers of cigarettes smoked, per day, per year) the greater the effect in terms of incidence of disease.

DUTY OF CARE
A legal responsibility to use reasonable care under all relevant circumstances in the development, design, manufacture and sale of consumer products.

ETS (ENVIRONMENTAL TOBACCO SMOKE)
A complex mixture of chemicals that appears in an environment (e.g. room) as a direct result of aged and diluted side stream smoke and exhaled mainstream smoke. (Sometimes also described as ambient smoke).

EPIDEMIOLOGY
The study of the incidence of disease and death in populations; the key science describing the risks of smoking.

EXPOSURE
Exposure to a substance means simply coming in contact. For cigarette smoking, exposure is measured first and foremost as Human Smoker Yield. Not all of an exposure may be taken up by the body and therefore not all of an exposure becomes biologically significant (this is Dose).

FCTC
Framework Convention for Tobacco Control.

HARM
Harm means causing physical or psychological damage or injury to a person, either permanently or temporarily.

HARM REDUCTION
Lessening the harm associated with risk taking behaviour without complete abstinence from that behaviour.

HUMECTANTS
Additives to the blend – most usually glycerol and/or propylene glycol – which improve moisture retention and can be used to dilute smoke.

INTAKE
Amount of substance taken up by the user, e.g. aerosol by vapes.

IN VITRO
Refers to biological studies conducted in a test tube or other artificial laboratory vessel, (as in 'in vitro', literally, 'in glass'). E.g. in vitro toxicity testing.

IN VIVO
Refers to studies conducted in a living body. E.g. in vivo animal testing.

IOM
Institute of Medicine in the U.S.A.

ISO
The International Organization for Standardization). A world-wide federation of national bodies covering standardization in all fields except electrical and electronic engineering standards. ISO is the world's largest non-governmental system for voluntary industrial and technical collaboration at the international level, and co-ordinates the exchange of information on international and national standards, technical regulations and other standards-type information.

METABOLITES
The biological breakdown products of an original substance. For example, the body metabolises nicotine in cotinine. Cotinine is a metabolite. See Biomarkers of Exposure.

MORBIDITY
The number of people with a particular disease in a population.

MORTALITY
The number of people who die of a particular disease in a population.

NICOTINE
The major alkaloid in tobacco. Nicotine in cigarette smoke is often expressed as milligrams of nicotine per cigarette. Nicotine in tobacco leaf is often expressed as a percentage on a dry weight basis.

PASSIVE SMOKING
The inhalation of ambient smoke, during breathing, generally by non-smokers.

PREP
Potentially Reduced Exposure Product, a term created by the US Institute of Medicine in 'Clearing the Smoke'. Defined as: 'A product that

I. results in the substantial reduction in exposure to one or more tobacco toxicants and
II. can reasonably be expected to reduce the risk of one or more specific diseases or other adverse health effects.

RISK
Risk is an estimate of the probability that harm will occur in a population usually estimated through epidemiological studies. It is typically difficult to determine the risk to an individual

SMOKELESS TOBACCO PRODUCTS
Non combustible tobacco products e.g. Snus

SNUS
A Swedish style of pasteurised smokeless tobacco, sold as loose tobacco or in portioned pouches, which is placed under the top lip where it releases nicotine and tobacco flavour.

TOBACCO SPECIFIC NITROSAMINES
See TSNA.

TOXICANT
A substance (e.g. from tobacco or its smoke) that is harmful to the body – may be poisonous or may cause cancer or other diseases.

TOXIN
A poisonous substance produced by living cells or organisms (N.B. should not be used in the context of tobacco or tobacco smoke)

TSNA'S
Tobacco Specific Nitrosamines are constituents found only in tobacco and tobacco smoke. Common examples are 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK), N'-nitrosoanatabine (NAT), N'-nitrosonornicotine (NNN), N'-nitrosoanabasine (NAB).

TOBACCO SPECIFIC TERMS

HEATED TOBACCO PRODUCTS OR OTHERWISE CALLED HEAT-NOT-BURN (HNB) PRODUCTS
Technology that generates a smoking aerosol by heating rather than burning tobacco and/or other smoking materials.

UKAS
United Kingdom Accreditation Service .

ANDS
Alternative Nicotine Delivery Systems (e.g., e-cigarettes, heat-not-burn tobacco)

E-CIGARETTES
also called vape pens, personal vaporizers, e-hookahs, e-pipes, and e-cigars, among other names, are battery-operated and produce an aerosol instead of smoke.

VAPING
the inhalation of e-cigarette aerosol

HARM MINIMIZATION
or reduction, aims to reduce health consequences without necessarily eliminating the behavior itself

NRT
Nicotine Replacement Therapy

TCA
The Family Smoking Prevention and Tobacco Control Act

FDA
Food and Drug Administration

CDER
Center for Drug Evaluation Research

U.K.
United Kingdom

DRY PUFF
conditions when vaping with a high wattage, too much airflow, old coils, or no liquid; not normally used

RCT
Randomized Controlled Trial

WHO
World Health Organization

HIV
human immunodeficiency virus

PRECAUTIONARY PRINCIPLE
resisting a new product with little known effects

NON-COMBUSTED/NON-COMBUSTIBLE TOBACCO
non-burning tobacco products (smokeless tobacco, snus)

APPENDIX A

Tobacco Harm Reduction Statements

Growing list of respected scientific and public health organizations that have reviewed all the evidence and concluded that nicotine is safer than smoking (and helps smokers quit)

All statements are hyperlinked to the original documents. Click the logo to view the original document.

World Health Organization EURO Office:
"There is conclusive evidence that: Completely substituting electronic nicotine and non-nicotine delivery systems for combustible tobacco cigarettes reduces users' exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes."

British Lung Foundation:
"Experts have reviewed all the research done on e-cigarettes over the past few years, and found no significant risks for people using e-cigarettes. ...Swapping cigarettes for an e-cig can improve your symptoms of lung conditions like asthma and COPD."

Royal College of General Practitioners:
"The evidence so far shows that e-cigarettes have significantly reduced levels of key toxicants compared to cigarettes, with average levels of exposure falling well below the thresholds for concern."

Public Health England:
"Our new review reinforces the finding that vaping is a fraction of the risk of smoking, at least 95% less harmful, and of negligible risk to bystanders. Yet over half of smokers either falsely believe that vaping is as harmful as smoking or just don't know."

Royal College of Physicians:
"Although it is not possible to precisely quantify the long-term health risks associated with e-cigarettes, the available data suggest that they are unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower than this figure... E-cigarettes are effective in helping people to stop smoking."

Royal Society for Public Health:
"RSPH has welcomed a new comprehensive evidence review on e-cigarettes published by Public Health England (PHE). The report reflects an up-to-date evidence base that is increasingly pointing in the same direction: not only that vaping is at least 95% less harmful than smoking, but also that it is helping increasing numbers of smokers to quit."

Cancer Research UK:
"While the long-term health consequences of e-cigarette use are uncertain, the evidence so far suggests that e-cigarettes are far less harmful than smoking. ...There is also growing evidence to suggest that e-cigarettes can work successfully as an aid to cessation. ...There is insufficient evidence to support a blanket indoor ban on e-cigarette use, either on the basis of renormalisation of smoking or harm to bystanders from second-hand vapour."

British Medical Association:
"Significant numbers of smokers are using e-cigarettes (electronic cigarettes), with many reporting that they are helpful in quitting or cutting down cigarette use. There are clear potential benefits to their use in reducing the substantial harms associated with smoking, and a growing consensus that they are significantly less harmful than tobacco use."

Action on Smoking and Health UK:
"It has been estimated that e-cigarettes are 95% less harmful than ordinary cigarettes. There is negligible risk to others from second-hand e-cigarette vapour. ...The lifetime cancer risk of vaping has been assessed to be under 0.5% of the risk of smoking. [But] Public understanding of the relative harms of e-cigarettes [vs smoking cigarettes] have worsened over time and are less accurate today than they were in 2014."

French National Academy of Pharmacy:
"The World Health Organization's [anti-e-cigarette] position is incomprehensible. Tobacco is responsible for 73,000 deaths in France. The e-cigarette helps people quit smoking. Its components are obviously less harmful than tobacco." [NOTE: This is a Tweet from the Académie Nationale de Pharmacie. Not an official statement.]

US Food & Drug Administration:
"Make no mistake. We see the possibility for ENDS products like e-cigarettes to provide a potentially less harmful alternative for currently addicted individual adult smokers who still want to get access to satisfying levels of nicotine without many of the harmful effects that come with the combustion of tobacco."

Government of Canada:
"Vaping is less harmful than smoking. Completely replacing cigarette smoking with vaping will reduce your exposure to harmful chemicals. There are short-term general health improvements if you completely switch from smoking cigarettes to vaping products."

US Centers for Disease Control:
"E-cigarettes have the potential to benefit adult smokers who are not pregnant if used as a complete substitute for regular cigarettes and other smoked tobacco products."

Royal Australian College of Physicians:
"The RACP acknowledges that e-cigarettes may have a potential role in tobacco harm reduction and smoking cessation for smokers unable or unwilling to quit."

Cochrane Tobacco Addiction Group (Cochrane TAG):
"No serious side effects were associated with [the use of e-cigarettes] (up to two years)."

Royal Australian & New Zealand College of Psychiatrists:
"Research shows that 70% of people with schizophrenia and 61% of people with bipolar disorder smoke compared to 16% of those without mental illness. ...E-cigarettes and vaporizers provide a safer way to deliver nicotine to those who are unable to stop smoking, thereby minimizing the harms associated with smoking tobacco and reducing some of the health disparities experienced by people with mental illness."

US National Academies of Sciences, Engineering and Medicine:
"While e-cigarettes are not without health risks, they are likely to be far less harmful than combustible tobacco cigarettes."

New Zealand Ministry of Health:
"The regulatory controls in the Smoke-free Environments Act 1990 were designed primarily for tobacco products that are smoked. They are inadequate for vaping and smokeless tobacco products, which are less harmful to users. There is an opportunity, through better regulation (and public information), to support smokers to switch to significantly less harmful alternatives, substantially reducing the risks to their health and those around them."

American Association of Public Health Physicians:
"Smoke-free tobacco/nicotine products, as available on the American market, while not risk-free, carry substantially less risk of death and may be easier to quit than cigarettes. ...Smokers who have tried, but failed to quit using medical guidance and pharmaceutical products, and smokers unable or uninterested in quitting, should consider switching to a less hazardous smoke-free tobacco/nicotine product for as long as they feel the need. Such products include pharmaceutical Nicotine Replacement Therapy (NRT) products used, off-label, on a long term basis, electronic "e" cigarettes, dissolvables (sticks, strips and orbs), snus, other forms of moist snuff, and chewing tobacco."

National Health Service Scotland consensus statement on e-cigarettes:
"Smoking kills. Helping people to stop smoking completely is our priority. ...There is now agreement based on the current evidence that vaping e-cigarettes is definitely less harmful than smoking tobacco."

This statement was created and endorsed by: Action on Smoking & Health Scotland • Cancer Research UK • Chest Heart & Stroke Scotland • Chief Medical Officer for Scotland • NHS Ayrshire and Arran • NHS Greater Glasgow and Clyde • NHS Lothian • NHS Tayside • Roy Castle Lung Cancer Foundation • Royal College of General Practitioners • Royal College of Physicians of Edinburgh • Royal College of Physicians and Surgeons of Glasgow • Royal Environmental Health Institute of Scotland • Scottish Collaboration for Public Health Research and Policy • Scottish Consultants in Dental Health • Scottish Thoracic Society • UK Centre for Tobacco & Alcohol Studies • University of Edinburgh • University of Stirling

American Cancer Society:
"Based on currently available evidence, using current generation e-cigarettes is less harmful than smoking cigarettes."

[NOTE: This was the official statement from 2018-2019. As of November 2019, ACS no longer recommends e-cigarettes as a smoking cessation tool. Their stated reason for this change was "e-cigarette use by young people." Illegal under-age use is undesirable, but does not change the original finding that nicotine vaping is less harmful than smoking.]

APPENDIX B

Tobacco Harm Reduction (THR) Case Study – Northern Hemisphere

Best Practice Tobacco Harm Reduction - England's Tobacco Control Plan

Photo by Luke Stackpoole on Unsplash

THR IN ENGLAND – ENGLAND'S TOBACCO CONTROL PLAN

England has adopted a broad-based comprehensive approach to tobacco control by adopting the main tools of established tobacco control. These include tobacco taxation; smoke free environments; advertising bans; standardised packaging; warnings and risk communications; support for smokers wishing to quit and some product regulation. However, what is different and interesting in England is the very positive approach taken to vaping and its role as a harm reduction approach in tobacco control. Harm reduction is recognised as integral to tobacco control in the World Health Organization (WHO) Framework Convention on Tobacco Control[1]:

> ***"1(d) '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)***

England is rightly seen as one of the world's most progressive backers of tobacco harm reduction (THR), where its approach covers law and regulation, taxation, communications, research and service provision. There is a broad consensus in favour of tobacco harm reduction among the main agencies and non-governmental organisations, including key players like Public Health England (PHE), Cancer Research UK (CRUK), the Royal College of Physicians (RCP), Action on Smoking and Health and a group of credible academics.

In 2017, the Department of Health (UK/England) released its Tobacco Control Plan for England: Towards a Smoke-Free Generation: Tobacco Control Plan for England[2] and followed up with a delivery plan.[3]

The plan highlights its support of vaping and other low-risk alternatives to smoking throughout. This is probably the first significant government policy paper anywhere that recognises and pursues the opportunities of tobacco harm reduction, rather than defining these technologies as a threat it needs to suppress. For that, the Department of Health and its allies deserve considerable credit.

EMERGENCE OF ENGLAND'S POSITIVE APPROACH TO VAPING

History is instructive, because it shows that decisions and leadership positions taken by consumers and by key individuals at decisive moments changed the course of policy. There was no single point at which the government in England decided to take a pro-vaping stance. In 2010, e-cigarettes became a visible political issue for the first time.

The Medicines and Healthcare Products Regulatory Agency (MHRA) noticed the presence of nicotine products on the UK market that were growing in popularity but were not licensed as medicines. It recommended that the products be regulated as medicines and those products without marketing authorisation (all e-cigarettes at the time) be taken off market in 21 days.

The MHRA consulted on the proposal[4], receiving submissions from the usual medical and health organisation supporting the de facto ban. But something else happened: over 1 000 consumers wrote in explaining their personal experience with e-cigarettes and imploring the regulator not to remove them from the market. These personal and visceral accounts cut through and the MHRA shelved its proposal.

However, it was shelved only until December 2012, when the European Commission brought out its proposal for a revision to the Tobacco Products Directive (TPD).[5] At that time, the TPD in force had been agreed in 2001, and it therefore predated the emergence of vaping products. The Commission proposed a single approach: regulate these products as medicines.

For regulators, this was simple and elegant – simply adopt an already existing regulatory framework and related institution, which was all achieved through neat cross reference between the new Tobacco Products Directive (nicknamed TPD-2)[6] and the Medicines Directive.[7] A perfect solution, but only if you are a bureaucrat. For consumers and producers, it was a nightmare. The basic problem is that vaping products are not medicines, their users are not patients and the manufacturers do not make therapeutic claims.

With one important exception, the manufacturers would be unable to bear the weighty burdens of a medicine regulation approval process. Nevertheless, the UK government decided in June 2013 that it would back the Commission's proposal and lined up with health organisations to back the medicalisation proposal.

As with the abortive attempt to impose medicine regulation in 2010, the proposed directive galvanised consumers and pro-harm reduction public health experts into a massive and ultimately successful, advocacy effort to defeat this measure in the European Parliament. This time, consumers from all over Europe wrote to their Members of the European Parliament (MEPs). They explained their personal experience and what these products had meant to them as they struggled with smoking. The personal consumer experiences cut through all the false and misleading claims about the risks of vaping that had been put to Parliament.

On 8 October 2013, the European Parliament rejected medicine regulation. The legislature then started an intense and secretive process of defining the measures that eventually became the framework for regulating vaping products at EU level, Article 20 of the revised Tobacco Products Directive.[6]

This began to change minds in England – consumer testimonies were so compelling and authentic that open-minded public health experts started to listen more carefully.

A decisive turning point was the first E-cigarette Summit, which was held on 12 November 2013 at the prestigious Royal Society in London. This brought vapers and public health experts together to discuss the issues and look at the science – both what was known and what was then unknown – in a meeting ably chaired by widely respected academic, Professor Ann McNeill.

However, the E-cigarette Summit produced something more subtle and valuable as well. It generated empathy, humility and the ability on the part of experts to 'walk in the shoes' of smokers and vapers and experience how they view the world. That shifted the expert community mindset towards seeing the opportunity as greater than the threat and starting to think positively about the potential for thousands and maybe millions of smokers to switch from smoking to vaping.

Through its experience in fighting battles over the future of vaping between 2010 and 2014, the consumer movement strengthened and built its own consumer organisation, the New Nicotine Alliance (founded February 2015).[8]
While consumers were fighting a very public and inspiring battle for the control over what was for them a life-or-death technology, there were also interesting developments at the highest levels in the UK government.

In 2010, e-cigarettes became a visible political issue for the first time.

In 2009, Number 10 Downing Street had set up a 'Behavioural Insights Team', which quickly became known as the 'Nudge Unit' after the famous book by Richard Thaler and Cass Sunstein.[9] The concept was to promote 'good' behaviours (stopping smoking, making sensible pension provision, conserving energy) by using 'nudges', or subtle changes to the 'choice architecture' – the way choices are presented to citizens.

As early as 2010, the Nudge Unit started to raise the prospects of e-cigarettes as a clever and cost-effective way of reducing the burden of smoking-related disease on the National Health Service. Moreover, it could secure policy goals by encouraging people to take responsibility for their own health on their own initiative and at their own expense. For modern policy makers, this is an ideal goal; involving the state as an enabler that uses its coercive powers to force behaviour change.

The idea received the backing of the UK's most senior civil servant, Sir Jeremy Heywood, the Cabinet Secretary[10] and eventually the then Prime Minister David Cameron.[11] There was, therefore, backing for policy innovation in the UK government at the very highest level.

Further developments included the successful introduction of vaping as an option at one of the Stop Smoking Services. Louise Ross, the manager of the smoking cessations service in Leicester, understood smokers and could really see this working. She became a vocal champion of harm reduction (and still is), with the backup of her direct, personal work in front-line public health.

This convinced many that there was an opportunity to revitalise these services with something that many smokers actually wanted to try. The UK's National Centre for Smoking Cessation and Training (NCSCT) went on to produce guidance on the role of e-cigarettes for professional smoking cessation services.[12]

The guide was produced with vapers' support and involvement. It is an excellent resource for anyone professionally engaged in smoking cessation.

Consensus-building Case Study: *As the consensus started to build in 2014, the lead advocacy organisation, Action on Smoking and Health (ASH), came around to the consumer perspective on public health grounds. Its, chief executive, Deborah Arnott became a champion, using her formidable diplomatic skills to build a coalition behind the idea. Cancer Research UK, the main cancer charity in the UK, was also in the process of re-evaluating its position, and again a courageous individual, Professor Linda Bauld, took the intellectual lead and brought Britain's large health charity into recognising the role for e-cigarettes in cancer prevention.*

Data supports Cancer Research UK in taking this stance: one study showed the cancer potency of 15 key carcinogens was 250 times lower (0.4%) in e-cigarette aerosol compared to cigarette smoke[12] Cancer Research UK recognised the opportunity for a novel strategy for addressing the single most important cause of cancer in the UK and embraced the tobacco harm reduction concept. Other major organisations joined to form a consensus position to align with a statement of high-level principles.[13]

The organisations included: Public Health England; Action on Smoking and Health; Association of Directors of Public Health; British Lung Foundation; Cancer Research UK; Faculty of Public Health; Fresh North East; Healthier Futures; Public Health Action (PHA); Royal College of Physicians; Royal Society for Public Health; UK Centre for Tobacco and Alcohol Studies; UK Health Forum.

In another decisive development, one of the key players in the advocacy organisation Action on Smoking and Health (ASH), Martin Dockrell, was seconded to Public Health England (PHE) to lead its tobacco control programme. Dockrell set about commissioning in-depth evidence reviews, which give the basis for policy in England in the years to come.

This included an initial assessment in 2014, and then the ground-breaking report[13] in 2015 in which PHE said that vaping was likely to be at least 95% lower risk than smoking. PHE continues to publish high quality evidence reviews[14] commissioned from the UK expert community.

The Royal College of Physicians (RCP) is justly famous for its 1961 report Tobacco and Health in which it set out in detail the known risks of smoking as they were understood at the time. That report and its equivalent from the US Surgeon General a year later altered the course of public health and started the concept of tobacco control. In 2016, it released a significant new report, Nicotine without Smoke: Tobacco Harm Reduction.[15]

This report confirmed the scientific basis to be positive about vaping, despite the residual unknowns. In particular, the RCP endorsed the low risk estimates of PHE, with the following carefully constructed formulation in Section 5.5, p.87[15]:

> ***Although it is not possible to precisely quantify the long-term health risks associated with e-cigarettes, the available data suggest that they are unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower than this figure."***

This statement recognises uncertainty in both directions ("unlikely to exceed", "may be substantially lower") so it is providing an anchor for relative risk perceptions but without being a single point estimate. The idea was to help physicians, consumers and the public more generally to get a feel for the consensus expert view of the relative risk of smoking and vaping. Although both PHE and RCP have been criticised for these estimates, it is normal practice to use numbers to communicate risk or to simplify complex science in order for people to have a sense of risk.

We do this, for example, with Body Mass Index or alcohol consumption guidelines. There were even claims the tobacco industry might be involved in these numbers somehow, but this was false – it was the judgement of the RCP's Tobacco Working Group and PHE's expert consultants, none of whom had links to the industry or any sort.

The Royal College of Physicians also gave an important piece of policy advice, which is taken more seriously in England than anywhere else. It concerns the risks of bad policy choices making the situations worse (Section 12.10, p.187)[15]:

> ***A risk-averse, precautionary approach to e-cigarette regulation can be pro- posed as a means of minimising the risk of avoidable harm, e.g. exposure to toxins in e-cigarette vapour, renormalisation, gateway progression to smoking, or other real or potential risks.***
>
> ***However, if this approach also makes e-cigarettes less easily accessible, less palatable or acceptable, more expensive, less consumer friendly or pharmacologically less effective, or inhibits innovation and development of new and improved products, then it causes harm by perpetuating smoking. Getting this balance right is difficult."***

Government officials in England were the first to recognise the issues raised by the Royal College of Physicians. In its regulatory impact assessment for the TPD-2[16], the government noted the potential for harmful unintended consequences:

> ***"207. There is a risk that due to the potential price increase and reduction of choice of e-cigarettes, people will choose to switch back to smoking, thus harming their health. This possibility is considered in the sensitivity analysis.***
>
> ***208. There is a risk that a black market will develop with potentially harmful e-cigarette products, due to consumers no longer having the same degree of choice in the legal market."***

Academic groups also played a significant, and probably decisive, role in consolidating support for vaping as a tobacco harm reduction for England. Researchers at Kings College London, University College London (UCL), Queen Mary College London, South Bank University and University of Nottingham produced high quality research and data.

In particular, the group, at UCL adapted the monthly smoking toolkit survey to measure the uptake and use of e-cigarettes giving a high-resolution picture of the use of e-cigarettes in England.

The academic leaders in England also share an intellectual heritage that originates from Professor Michael Russell, who died in 2009. Professor Russell memorably coined one of the great catch phrases of tobacco harm reduction as early as 1976: "People smoke for the nicotine but die from the tar."[17]

ENGLAND'S TARGETS ARE FOCUSED ON SMOKING

The single most important aspect of England's approach to tobacco control is the overriding focus on smoking. This is because the purpose of tobacco control is to reduce premature death and serious disease. Smoking – the inhalation of the products of combustion of dried and cured tobacco leaf – is by far the dominant cause of disease and premature death.

It is important, therefore, to recognise what is not the priority. The policy does not give primacy to reducing nicotine use or reducing all tobacco use. This is important because there are potential trade-offs to be made between objectives. For example, if it were possible to reduce smoking by using safer forms of nicotine, the goal of reducing smoking would prevail over the goal of reducing nicotine use.

This is reflected in the goals of the Tobacco Control Plan[2], which are to, by the end of 2022:

- Reduce the prevalence of 15-year olds who regularly smoke from 8% to 3% or less.
- Reduce smoking prevalence amongst adults in England from 15.5% to 12% or less.
- Reduce the inequality gap in smoking prevalence between those in routine and manual occupations and the general population.
- Reduce the prevalence of smoking in pregnancy from 10.5% to 6% or less."

The focus on smoking, rather than on nicotine, tobacco use or other goals is appropriate from a public health perspective, because smoke causes the harm and this gives clarity to the policy framework.

The way the targets are specified, therefore, does not preclude the use of reduced-risk tobacco and nicotine products to achieve the smoking-related targets. This idea is explicitly endorsed in support of tobacco harm reduction.

DATA AND MONITORING

England has excellent data resources monitoring levels of smoking, vaping and other forms of nicotine use. There is also good data on behaviours. For example, three main sources stand out relating to intention and attempts to quit smoking as well as on beliefs and attitudes:

- The Office of National Statistics and Public Health England collaborate and include questions about smoking and vaping in major household surveys. It also provides headline prevalence figures and local-level data[18][19];
- The Smoking Toolkit Survey, Smoking in England[20], measures a range of smoking, vaping and quitting behaviours. Academics at the University College London conduct the survey monthly; and
- Action on Smoking and Health collaborates with YouGov to provide annual surveys[21][22] of use, behaviours, risk perceptions and attitudes.

Current data from the authoritative ONS surveys[18][19] show very positive progress in smoking and vaping trends:

- UK adult (≥ age 18) smoking prevalence fell from 20% in 2011, to 14.7% in 2018; and
- Number of smokers 2018 = 7.2 million.

Vaping prevalence is measured in a different survey (Opinion and Lifestyle Survey). This covers 16 000 households in Great Britain (GB = England, Scotland, Wales, excluding Northern Ireland) and focuses on adults ≥ age 16:

- Vaping prevalence reached 6.3% in 2018 – a rise from 3.7% in 2014 and very low levels in 2011; and
- Number of vapers in 2018 = 3.2 million

Vaping has become a large-scale phenomenon relative to smoking and appears to be placing significant downward pressure on smoking rates. In England, we are witnessing tobacco harm reduction in action and starting to benefit from a public health win.

EVIDENCE-BASED SUPPORT FOR THR

In its Tobacco Control Plan, the UK government explicitly commits to an evidence-based approach and argues that this leads directly to endorsement of tobacco harm reduction. As stated on p.5 of the policy[2]:

"4. Backing evidence based innovations to support quitting "We are committed to evidence-based policy making, so we aim to:

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

This is further supported by the following on p.15[2]:

> ***"The best thing a smoker can do for their health is to quit smoking. However, the evidence is increasingly clear that e-cigarettes are significantly less harmful to health than smoking tobacco. The government will seek to support consumers in stopping smoking and adopting the use of less harmful nicotine products."***

This stance embraces the opportunity of new technologies instead of defining them as threat. However, the position is not unconditional: it is contingent on foundations to support evidence and monitor the marketplace for adverse effects. This can be found on p.16[2]:

> ***"DH [The Department of Health] will monitor the impact of regulation and policy on e-cigarettes and novel tobacco products in England, including evidence on safety, uptake, health impact and effectiveness of these products as smoking cessation aids to inform our actions on regulating their use."***

> ***"DH [The Department of Health] will, based on the evidence reviews undertaken by PHE, review policy and regulation of nicotine delivery systems to provide an environment that facilitates smokers taking action to improve their health and the health of those around them, whilst minimising any risk of new nicotine addiction in children."***

As well as looking for problems or benefits arising from the products, this will also include assessment of the policies. This means the government will also monitor for harmful unintended consequences of regulation and respond accordingly.

To this end, Public Health England will update its evidence reports on e-cigarettes and other novel nicotine delivery systems annually until the end of the Parliament in 2022 and will include within quit smoking campaigns messages about the relative safety of e-cigarettes.

Evidence updates (see 2015 version) that cut through the detached academic activism and media clickbait about vaping are playing an important role in responsible government policy.

INDOOR VAPING – LET PROPERTY OWNERS DECIDE POLICY

There is no robust evidence of material harm from second-hand vapour. The vapour is much less toxic than cigarette smoke and there is no 'side stream' vapour released from the device while not in use by the users. Cigarettes burn continuously at the tip, releasing smoke even when not in use.

It is not just an absence of evidence of harm: the available evidence suggests that the possibility of material harm from second-hand vapour would be minimal. On the other hand, second-hand cigarette smoke – especially the smoke generated when a user is holding a lit cigarette – has been associated with cancer and heart disease in bystanders. For example, one study[23] estimated lifetime cancer risk from passive vaping compared to passive smoking. The difference was of the order of 10 000 times, i.e. negligible:

> ***"ECLR [Excess Lifetime Cancer Risk] for passive smokers is 5 orders of magnitude higher than the passive vaper."***

Even if e-cigarette vapour contains traces of hazardous agents, they are present at such low concentrations in exhaled vapour that they pose no meaningful risk to bystanders when compared to occupational exposure limit values (a benchmark of acceptable risk).[24]

The primary issue with vaping is one of nuisance rather than a material health threat. Placing excessive restrictions on where people can vape is a potential source of unintended consequences. If smokers were trying to switch from smoking to vaping, it would raise the chance of distraction or relapse.

In the absence of material risk to the health of bystanders, there is a very weak justification for a mandated regulatory approach in which a general prohibition would override the preferred approaches of property owners and managers. Consider the following approaches to vaping in Figure 1:

A bar wants to have a vape night every Thursday.

A bar wants to dedicate one room where vaping is permitted.

A smoke-free corrections facility wants to support inmates to manage nicotine withdrawal and related tensions by allowing them to vape.

In a town with three bars, one decides it will cater for vapers, two decide they will not allow vaping.

A bar manager decides on balance that his/her vaping customers prefer it and his/her other clientele are not that bothered – he'd do better by allowing it.

A hotel wants to allow vaping in a few rooms and in its bar, but not in its restaurant.

An office workplace decides to allow vaping breaks near the coffee machine to save on wasted smoking break time and encourage smokers to quit by switching.

A care home wants to allow an indoor vaping area to encourage its smoking elderly residents to switch during the coming winter.

A vape shop is trying to help people switch from smoking and wants to demo products in the shop.

Vaping might be permitted in railway stations or airport terminals, but not on trains and aircraft.

Many shops, public buildings and places catering for children decide not to allow vaping at all.

Figure 1: Hypothetical examples of 'bottom up' vaping policies

The argument is that there is no good rationale to override these reasonable decisions with a blanket prohibition when there is no plausible material risk to bystanders. The absence of a legislated ban does not create a 'right to vape', but it makes the vaping policy in any space a matter for the owner or manager rather than for government or legislature.

Public Health England (PHE) has offered guidance for employers and organisations looking to introduce policies around e-cigarettes and vaping in public and recommends that such policies should be evidence-based.[25]

PHE also recommends that e-cigarette use not be covered by smoke-free legislation and not be routinely be included in the requirements of an organisation's smoke-free policy. In addition, Action on Smoking and Health (UK) produced a set of structured questions to guide employers through vaping policy options.[26]

PHE will support local areas looking to implement local smoke-free policies differentiating the levels of harm caused by existing tobacco products, including e-cigarettes and other novel products.

This recognises that decisions on vaping policy should rest with owners and managers of properties and steers them not to include vaping in organisational smoke-free policies by default.

This implicitly acknowledges that there is no justification (for example, material harm to bystanders or workers) to override the preferences of property owners with blanket vape-free laws. This is an ethically robust position to take.

Photo by Robert Bye on Unsplash

> "As alternatives to smoking, e-cigarettes function as a form of stop-smoking technology."

MARKETING RESTRICTIONS ON VAPING PRODUCTS

The United Kingdom is bound by the European Union Tobacco Products Directive and its restrictions on the advertising, promotion and sponsorship of vaping devices and e-liquids (these are detailed Article 20(5) of Directive 40/14/EU).[27] These provisions essentially ban advertising in any medium capable of crossing a border – TV, radio, internet, publications, etc.

The Directive does not have jurisdiction over advertising that is fixed within a member state – billboards, point-of-sale, etc. The UK abides by the directive, but England has taken a more permissive approach to the advertising that is not covered by the Directive.

Heated tobacco products are classified as tobacco products and all advertising of these products is banned by default because it is covered by the legislation designed to eliminate advertising of cigarettes.

The starting point for policy makers is to be clear on what the policy is supposed to achieve – what is the risk it is supposed to address. Advertising of cigarettes is largely banned in the EU because smoking kills 700 000 EU citizens annually. Advertising is thought to increase the appeal of this product. It may therefore, potentially mean that more people smoke, smoke more, smoke for longer or do not quit as soon as they might. Many activists have simply argued for applying the same measures to vaping products as to tobacco products. However, the basic justification – that smoking causes death and disease – is simply not valid for e-cigarettes.

These justifications for bans or restrictions on cigarette advertising cannot simply be applied to e-cigarette advertising or to any reduced risk product.

As alternatives to smoking, e-cigarettes function as a form of stop-smoking technology. Advertising for e-cigarettes is a form of anti-smoking advertising. A ban on e-cigarette advertising might, therefore, be damaging to public health. It would result in erecting barriers to entry to a new and disruptive technology (vaping products) in a market dominated by a harmful and entrenched incumbent (cigarettes). Again, it is essential for policymakers to adopt an open-minded approach to unintended consequences of what seem like positive policies on the surface.

The UK's approach to e-cigarette advertising was adopted by the UK Committee on Advertising Practice (CAP) in 2014. The starting point is that conventional "legal, honest, decent, truthful" standards should apply, as they do to all advertising.

That is, in itself, a significant protection. The CAP also produced useful guidelines on e-cigarette advertising that provide a reasonable balance of interest between protection of minors and promotion of new low-risk products to smokers. Its framework[28] [29] is somewhat similar to the controls on alcohol advertising, that control aspects of content and placement, but do not impose outright bans.

A hugely positive development is that the CAP recently consulted on allowing certain health claims to be permitted. This draws a distinction between therapeutic claims (e.g. helps to stop smoking) and health claims (e.g., vaping greatly reduces exposure to carbon monoxide). It therefore allows truthful and evidence-based statements to be made in advertising.[30]

If the regulation of e-cigarette advertising had purely been a UK matter, then it is likely England would already have a workable and proportionate system. Unfortunately, through the Tobacco Products Directive, the EU has put an outright ban on all forms of advertising capable of crossing a border.

RISK-PROPORTIONATE TAXATION OF NICOTINE PRODUCTS

The UK has one of the highest tobacco tax regimes in Europe and the wider world. In September 2019, a pack of 20 Marlboro cigarettes sold for around £11.50 (€13.00). Of this, £3.12 was the pre-tax price and £8.38 was the tax, the excise duty plus value added tax. Tax makes up approximately 73% of the price. Budget cigarettes are cheaper but carry a higher burden of tax.

There are strong reasons not to tax reduced-risk alternative smoke-free nicotine products at all. This would reflect their value in supporting smoking cessation and addressing ethnic and socio-economic health inequalities. In the UK, over-the-counter nicotine replacement therapy (NRT) even attracts a tax subsidy, a reduced rate of value added tax (VAT), for its perceived value in reducing smoking.

High and regressive tobacco taxation that falls disproportionately on poor or marginalised ethnic groups poses formidable ethical challenges. For users, the obvious mitigating response has been to seek out illicit untaxed supply or down trading to tobacco products that attract lower duties (typically, hand-rolling tobacco or 'budget' brands).

However, it is important to have as many lawful options as possible to mitigate the unfairness implicit in tobacco taxation – that includes facilitating low-cost pathways to switch from smoking to low risk alternatives. For that reason, we recommend a system of risk-proportionate taxation be implemented, as advocated by Chaloupka, Sweanor and Warner.[31]

So far, the UK has stuck loosely to the principles of risk proportionate taxation, though there is still room for improvement. Nicotine replacement therapy sold over the counter attracts a tax subsidy – NRT attracts a reduced rate of VAT: 5% compared to the standard 20%. The evidence to support a tax discount for NRT sold over the counter is very weak.

- Non-pharmaceutical, non-tobacco oral nicotine products (for example, Zyn) attract no excise duty, but the full 20% rate of VAT is applied. These products are rising in popularity in many markets but are not yet significant in the UK.

- E-cigarettes attract no excise duty, but the full 20% rate of VAT is applied. Depending on the approach taken, vaping can be as much as 90% cheaper than smoking. Economic factors are understood to be a major driver of switching and can provide a significant economic benefit to poor households – they may be important in addressing health and welfare inequalities.

- Heated tobacco products attract both excise duty and VAT. However, a separate category has been defined for heated tobacco products, so this allows for risk-based differentiation in future. The excise duty is currently at the same level as hand-rolling tobacco on a weight basis: £234.65 per kg (September 2019). However, because relatively small amounts of tobacco are used in the heated tobacco consumables, the price of heated products like iQOS is about half that of the equivalent cigarettes.

- Chewing tobacco attracts a lower excise duty than cigarettes or heated tobacco, £125.20 per kg. However, the main issue with smokeless tobacco is that oral tobacco (snus) is banned throughout the European Union, with the exception of Sweden. This is despite the low levels of smoking and smoking-related disease in Sweden that is attributable to snus.

The UK New Nicotine Alliance (NNA) of consumers has advanced a powerful case[32] to adopt risk-proportional taxation. The NNA has set out key principles it wants to see adopted by the government.

1. **The tax regime has implications for human life.** Given cigarettes and smoke-free alternatives are substitute products there will be positive price cross-elasticities between smoking and smoke-free products. A significant tax on smoke-free products will cause a relative increase in the demand for combustibles – and therefore, will, cause more smoking. The default excise rate should be zero, proceeding with caution if higher rates are proposed.

2. **Setting the level: the highest level applied to any smoke-free product should be substantially lower that the lowest rate applied to any combustible product.** This entails maintaining a significant differential – between the cost of being a smoke-free product user and a smoker – to preserve an incentive to switch and avoid developing a black market or encouraging homemade production.

3. **Recognise cost burdens of tax administration.** Vaping is likely to have at least a 95% lower risk than smoking. If excise duties were set, proportionate to risk that is relative to smoking to create a proportionate deterrent, then the tax yield for e-cigarettes would be so low it would not be worth the collection costs. The only way to make a non-zero tax viable is to tax smoke-free products disproportionately to their risk, thereby imposing a disproportionate deterrent to users switching.

4. **Comparison with NRT** – therapeutic value. Smoke-free products actually produce a net health benefit by reducing smoking. From an economic and tax perspective, such products should be viewed more like over-the-counter medicines. Some jurisdictions apply a reduced sales tax to nicotine replacement therapy – i.e. a tax subsidy – to reflect its positive public health value.

It is argued that because tax-take is decreasing from cigarettes as people switch or quit, then excise duty should be applied to alternative products to compensate. This does not have an economic rationale, even if it has superficial political appeal. Tax should be raised from the least distorting and most efficient tax base available. There is no reason why cigarette excise losses should not be recovered from taxes on, for example, carbon dioxide, fuel charges, removal of tax subsidies or by cutting spending that is less cost-effective than reducing smoking.

INNOVATION AND HEATED TOBACCO PRODUCTS

The Tobacco Control Plan[2] recognises the potential value of innovation. This is an important feature of tobacco policy because many jurisdictions have erected substantial barriers or even outright prohibitions of products like e-cigarettes or heated tobacco products. As stated on p.15 of the plan[2]:

> ***"In addition, there has been the development and very recent introduction of novel tobacco products that claim to reduce the harm of smoking. We welcome innovation that will reduce the harms caused by smoking and will evaluate whether products such as novel tobacco products have a role to play in reducing the risk of harm to smokers."***

The UK is open-minded about innovation that could reach more people with a product they find acceptable and pleasurable. However, the UK has not shown that it has a fully open mind about tobacco harm reduction. It supported the ban on oral tobacco (Swedish snus), despite extensive evidence that snus is responsible for Sweden's anomalously low rate of smoking (5% daily smoking in Sweden compared to an average of 24% in the European Union).[33]

MEDICALISATION AND TREATMENT USING E-CIGARETTES

Despite a battle over medicalisation of e-cigarettes in 2010 and 2013, the UK government still sees this as an important route to market that is allowed under the Tobacco Products Directive, p.16[2]:

> ***"DH will provide evidence based guidance for health professionals to support them in advising smokers who want to use e-cigarettes or other nicotine delivery systems to quit.***
>
> ***"The Medicines and Healthcare products Regulatory Agency (MHRA) will ensure that the route to medicinal regulation for e-cigarette products is fit for purpose so that a range of safe and effective products can potentially be made available for NHS prescription."***

The tension over medicalisation is no longer there as long as it is available as a parallel track and not a mandatory pathway. Products with a medical marketing authorisation may be used more readily in healthcare settings or even prescribed as treatment options. It is possible that they could also have product specifications and marketing approaches that would not be permitted under the Tobacco Products Directive, for example, higher nicotine strength than the 2% limit imposed by the Directive.

The key issue here is the need for a positive approach by health and medical professionals – what they say needs to be realistic and patient-focused. England already has good officially endorsed guidance on e-cigarettes for health professionals and it will be very helpful to have this updated routinely. Simplifying the medical licensing option is of lesser importance, but could provide some benefits within health care settings, but only as long as it remains an option.

ADVICE TO HEALTHCARE PROFESSIONALS AND USERS

Tobacco control professionals and public sector practitioners now recognize that e-cigarettes can be used constructively to reduce harm. In Britain, for example, the National Centre for Smoking Cessation and Training and the government's public health agency Public Health England, have developed evidence-based guidance and training for health and smoking cessation professionals.[12][34] This provides a clear and measured assessment of the state of science and best practice. The advice given to UK health professionals by the National Centre for Smoking Cessation and Training and Public Health England is summarised[12]:

Recommendations for practice:

1. Be open to e-cigarette use in people keen to try them; especially in those who have tried and failed to stop smoking using licensed stop smoking medicines.
2. Provide advice on e-cigarettes that includes the following key information:
   - E-cigarettes provide nicotine in a form that is much safer than smoking;
   - Some people find e-cigarettes helpful for quitting, cutting down their nicotine intake and/or managing temporary abstinence;
   - There is a wide range of e-cigarettes and people may need to try various types, flavours and nicotine dosages before they find a product that they like;
   - E-cigarette use is not like smoking. People may therefore, need to experiment and learn to use them effectively (e.g. they may need to take longer "drags" and need several initial short puffs to activate the vaporiser and improve nicotine delivery). They may also need to recognise when atomisers need replacing;
   - People previously using e-cigarettes while smoking (e.g. to reduce the number of cigarettes they smoke) may need to consider changing devices and/or nicotine concentrations when attempting to quit; and
   - Although some health risks from e-cigarette use may yet emerge, these are likely, at worst, to be a small fraction of the risks of smoking. This is because e-cigarette vapour does not contain the products of combustion (burning) that cause lung and heart disease, and cancer.

The UK's widely respected National Health Service (NHS) has also taken up the cause and provides pragmatic advice and factual information to smokers looking to quit. The NHS has incorporated vaping as a harm reduction strategy in its 'Live Well' advice and 'One You' campaign.

In addition, Public Health England has incorporated vaping into the annual government-backed stop-smoking campaign 'Stoptober'.

Stoptober embraced e-cigarettes in October 2017, becoming the first government-backed smoking cessation campaign to advertise the idea of vaping to quit smoking on television.

This balanced and open-minded approach reflects an emerging consensus on how to exploit the opportunities of e-cigarettes, while containing any risks. More examples of innovative public sector initiative are available via a page devoted to England on the Counterfactual website.[35]

Photo by Fred Moon on Unsplash

BREXIT AND UK TOBACCO POLICY

The government believes that some aspects of its policy could be improved and that the constraints imposed by the EU Tobacco Products Directive should be removed.

As per p.27 of the Tobacco Control Plan[2]:

> ***"Review where the UK's exit from the EU offers us opportunities to further improve public health***
> *Over the course of this Tobacco Control Plan, the government will review where the UK's exit from the EU offers us opportunities to re-appraise current regulation to ensure this continues to protect the nation's health. We will look to identify where we can sensibly deregulate without harming public health or where EU regulations limit our ability to deal with tobacco.*
>
> *In particular, the government will assess recent legislation such as the Tobacco Products Directive, including as it applies to e-cigarettes, and consider where the UK's exit provides opportunity to alter the legislative provisions to provide for improved health outcomes within the UK context."*

The government believes that some aspects of its policy could be improved and that the constraints imposed by the EU Tobacco Products Directive should be removed.

This might provide the opportunity, for example, to lift some EU-imposed restrictions that have no support in evidence. These include bans on advertising, limits on nicotine strengths, excessive warnings and limits on tank and container size.[36], Member of the European Parliament (MEP)]

Depending on the precise form of Brexit that the UK takes, it may result in a more pessimistic view of Brexit as it relates to vaping.[37] For example, the UK may possibly remain in a lengthy transitional period or required measures to secure an open border between Ireland and the UK in Northern Ireland (the 'backstop') will mean that the UK stays in close regulatory alignment with single market regulation. That would likely include the Tobacco Products Directive.

However, in doing so, the UK would also become a 'policy-taker' and be excluded from negotiations and voting on new measures. The UK could therefore, find itself complying with a new version of the Tobacco Products Directive in the mid-2020s without having had much say in its development. It is likely that losing the UK voice at the table will be disadvantageous to vapers and smokers across the European Union. The EU will lose a champion of the rational and pragmatic harm reduction approach. This would increase the relative weight of abstinence-only ideological perspectives in the decision-making.

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APPENDIX C

Tobacco Harm Reduction in the South

(Lower and Middle Income Countries or LMICs)

INTRODUCTION: THE GREATEST PUBLIC HEALTH CHALLENGE

The current population of the African continent is 1.3 billion people[1]. There are an additional 411 million people in the Middle East, a region of around 17 countries.[2] One of the most important questions to ask is what the major causes of morbidity and mortality in these regions are, and what can be done to prevent disease and save premature deaths?

In this regard, one of the main problems affecting these regions is the use of combustible tobacco. Switching to less harmful forms of nicotine delivery systems and/or quitting tobacco altogether can save hundreds of millions of lives.

This case study aims to provide the context and rationale for tobacco harm reduction (THR) and outline less harmful nicotine delivery systems in Africa and the Middle East.

WHAT HARM DOES TOBACCO USE CAUSE?

Smoking is the single most serious cause of non-communicable diseases – cancer, cardiovascular disease and respiratory illnesses. Users are harmed through inhalation of smoke and some harm is also done to bystanders through exposure to second-hand smoke ("passive smoking").

According to the World Health Organization (WHO), smoking causes six million premature deaths annually[3], and it estimates that the death toll on current trends will reach one billion in the 21st Century.[4]

OFFICIAL TARGETS TO REDUCE TOBACCO USE AND NON-COMMUNICABLE DISEASE

Non-communicable diseases (NCDs) – mainly cardiovascular diseases, cancers, chronic respiratory diseases and diabetes – are the biggest cause of death worldwide. More than 36 million people die annually from NCDs (63% of global deaths), including 14 million people who die prematurely before the age of 70.

More than 90% of these deaths from NCDs occur in low and middle-income countries, and most could have been prevented. Most premature deaths are linked to common risk factors, namely tobacco use, unhealthy diet, physical inactivity and harmful use of alcohol.[5]

In a series of political declarations, the members of the UN General Assembly in 2011[6] and World Health Assembly in 2013[7][8] committed to taking concerted action to reduce the burden of NCDs. They undertook to do this by attaining nine voluntary global targets[9], including an over-arching target to reduce non-communicable disease mortality and tobacco use. All member states, including every African and Middle Eastern nation agreed to these objectives.

For example, Egypt, with an estimated 18% adult smoking prevalence (mainly men) in 2010, would aim to achieve 18% x (1 – 30%) = 12.6% prevalence by 2025. Note that with population growth this would not mean reducing the number of smokers by 30%, but by less.

CHALLENGES IN MEETING THE NCD TARGETS

Worldwide, smoking prevalence in people aged 15 and over was estimated at 22% in 2012[10] and this will be tough to reduce. The target is to reduce smoking prevalence by 30% in relative terms – to 15.4% - by 2025 globally. This section examines some specific issues as they relate to Africa and the Middle East.

Table 1: Relevant non-communicable disease targets

FRAMEWORK ELEMENT	TARGET	INDICATORS
Target 1: Non-communicable diseases	A 25% relative reduction in the overall mortality from cardiovascular diseases, cancer, diabetes, or chronic respiratory diseases by 2025 compared to 2010.	• Unconditional probability of dying between the ages of 30 and 70 from cardiovascular diseases, cancer, diabetes or chronic respiratory diseases; • Cancer incidence, by type of cancer, per 100 000 population.
Target 5: Tobacco use	A 30% relative reduction in the prevalence of current tobacco use in persons aged 15+ years by 2025 compared to 2010.	• Prevalence of current tobacco use among adolescents; • Age-standardised prevalence of current tobacco use among persons aged 18+ years.

The target will be extremely difficult to meet

It is extremely challenging to achieve a major structural change in the aetiology of disease in 15 years. It is likely that the targets are more political than grounded in evidence of what works and how rapidly transitions can take place. A reduction in tobacco prevalence of 30% over 15 years is exceptionally difficult. This represents an annual decline of 2.35% compounded over 15 years. The problem is that this aspiration contradicts recent experience.

For example, in the period 2000-2012, the average reduction in smoking prevalence in countries in Africa and the Middle East was just 0.6% per year (unweighted). In fact, smoking prevalence increased in 23 countries in Africa while the Middle East decreased by less than 2.35% per year in 36 countries.

The prevalence decreased more rapidly than 2.35% per year in only six countries: Senegal, Nigeria, Uganda, Madagascar, Algeria and Rwanda.[11] This experience in Africa and Middle East is typical of the global picture. Table 2 below shows annual rates of decline in developed and developing countries.[12]

Table 2: Historic rate of change of smoking prevalence

ANNUALISED PERCENTAGE RATE OF CHANGE IN AGE-STANDARDISED SMOKING PREVALENCE	1980-1996	1996-2006	2006-2012
Global	-0.4	-1.7	-1.7
Developed countries	-1.0	-1.7	-1.1
Developing countries	-0.2	-1.7	-0.7

It is evident that recent historic rates of decline have been far below the annual 2.35% rate of change envisaged in the NCD target for tobacco use. In addition, the rate of decline slowed down more recently in the 2006-2012 period, which coincides with the implementation of the WHO's Framework Convention on Tobacco Control. Recent reports suggest that smoking prevalence may actually be rising in Africa[13] and in the Gulf states,[14] which is confirmed by projections made by the WHO.[15]

(see figure 1)

At a rate of 0.7% reduction per year, the decline over 15 years would be just 10% - only one third of the UN's goals. Given that the world population is projected to rise by 17% from 2010 to 2025, then it is possible to reduce prevalence by up to 1.2% per year and have more smokers in 2025 than in 2010.

It is likely that a new and additional approach will be necessary if nations are to come even close to meeting the UN targets to reduce tobacco prevalence by 30%. This approach will focus on reducing disease risks to people who continue to use tobacco or nicotine, and will complement other tobacco control efforts.

PROJECTED CHANGE IN ADULT SMOKING PREVALENCE 2010-25 (WHO)

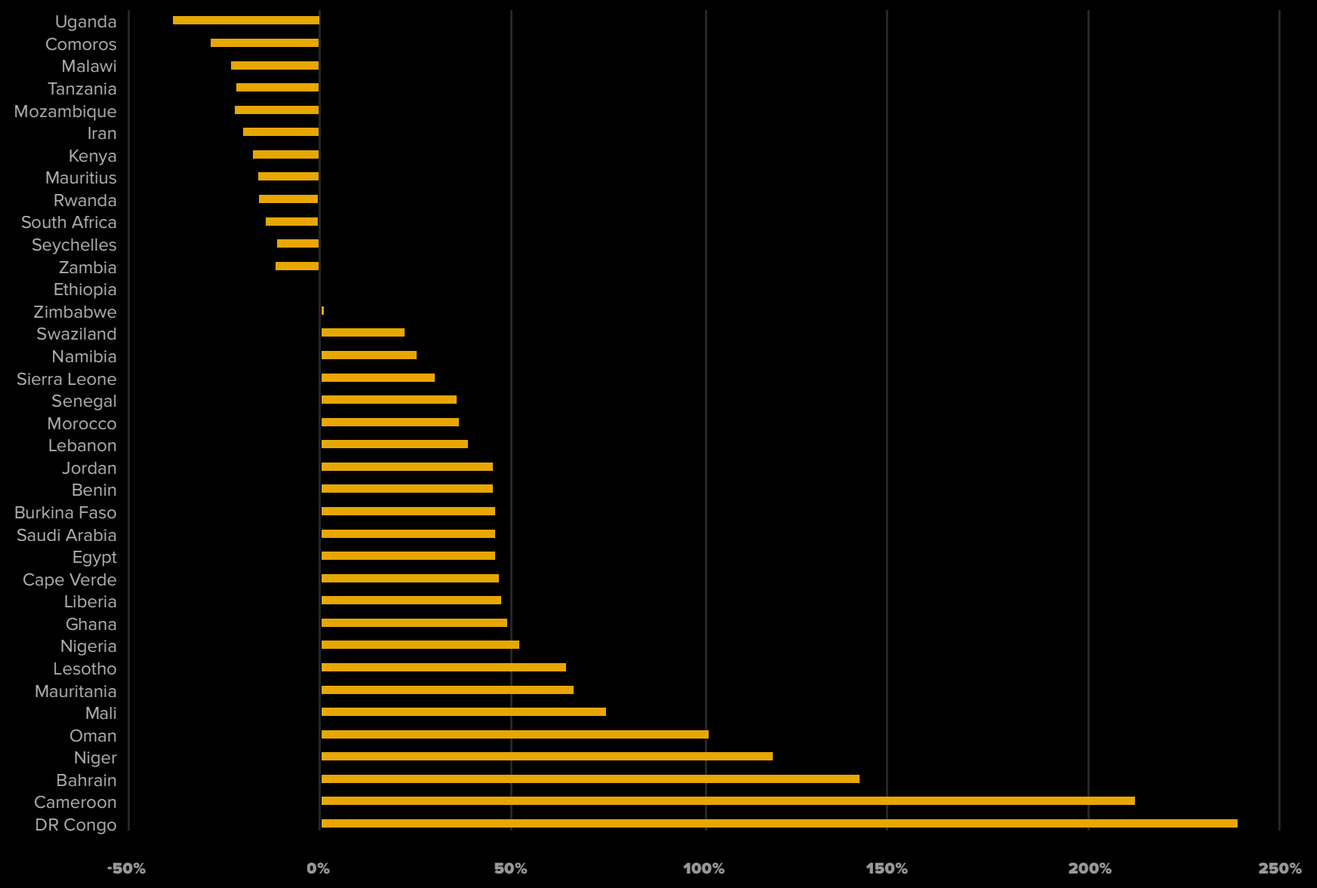
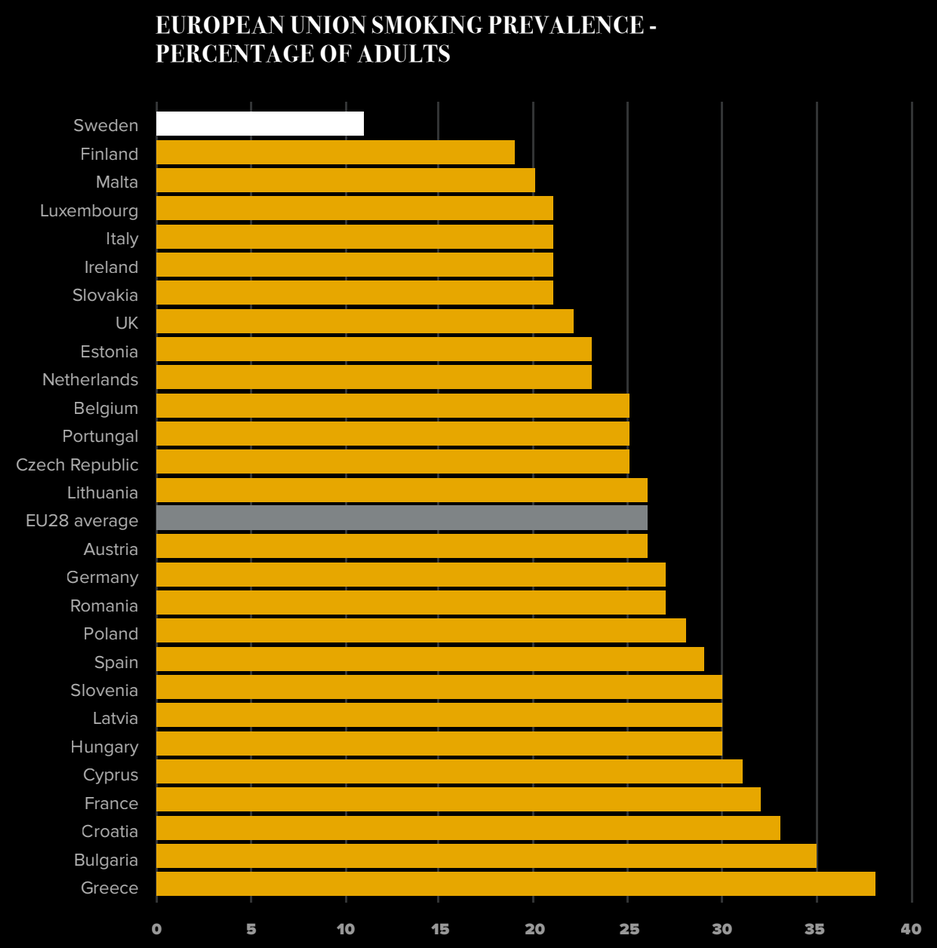


Figure 1: Projected change in smoking prevalence in African and Middle Eastern countries
Source: World Health Organization, 2015



Source: European Commission, Eurobarometer 429, May 2015 - Fieldwork Nov-Dec 2014
Q: Regarding cigarettes, cigars, cigarillos or a pipe, which of the following applies to you?
In this question smoking cigarettes does not include the use of e-cigarettes
A: You currently smoke.

Figure 2: Illustrating the role smokeless tobacco plays in reducing smoking: Sweden[16]

The targets are in conflict
The primary NCD target is specified in terms of disease and mortality outcomes. However, the target for modifying the risky behaviour is specified in terms of tobacco use, whereas the disease is overwhelmingly caused by smoking. This creates a problem if there are forms of tobacco use that can substitute smoking and are much less risky. This refers to the "harm reduction" concept discussed in greater depth later.

This is a clear problem, both in theory and in reality. It is well understood that a smokeless tobacco product, snus, is responsible for Sweden having by far the lowest rates of smoking among the developed countries *(see the European Union data*[16] *in Figure 2)* and the lowest rates of cancer and cardiovascular disease.[17] Compared to smoking, the risk to snus users is very low indeed.[18]

(see figure 2)

The problem extends to other forms of tobacco that have the potential to be a substitute for smoking but present much lower risks. For example, heated tobacco products or tobacco lozenges contribute to meeting Target 1 (overall non-communicable diseases mortality) but do not contribute to Target 5: Reducing tobacco prevalence.

The NCD and tobacco targets are partly in conflict. Either the tobacco target should change to focus on smoking, or governments should give precedence to the focus on disease and ignore or reinterpret the tobacco target.

Data collection and analysis
A major challenge will be the collection of data – including estimates of baseline data for 2010. This will be particularly difficult in Africa and the Middle East, where data collection has been sporadic at best. The WHO has produced a global status report[10] and a series of country report cards.[19]

In addition, it has established institutional machinery to track progress and encourage action. However, the quality of coverage and frequency of the data collection is far from adequate to address the challenge. Moreover, it makes it difficult to understand what transitions tobacco users are making, and whether these are beneficial to health.

In poorer countries, the statistical monitoring of tobacco and nicotine use and transitions over time is a major public health priority. This is an area where tobacco companies could fund independent surveys that external experts have designed or validated.

TOBACCO USE IN AFRICA AND THE MIDDLE EAST

The data available to characterise smoking and other forms of tobacco use in Africa and the Middle East are often very poor. In many instances, they merely consist of projections from sales data or other crude estimates. However, the Institute of Health Metrics and Evaluation (IHME) has made a concerted effort to piece together estimates of smoking prevalence and other relevant data.[11][12] These estimates, though complete, are not direct measurements, but the best efforts with the available data and with large margins of error.

SMOKING PREVALENCE

The maps below place smoking prevalence in Africa and the Middle East in a global context and show that the picture is mixed.

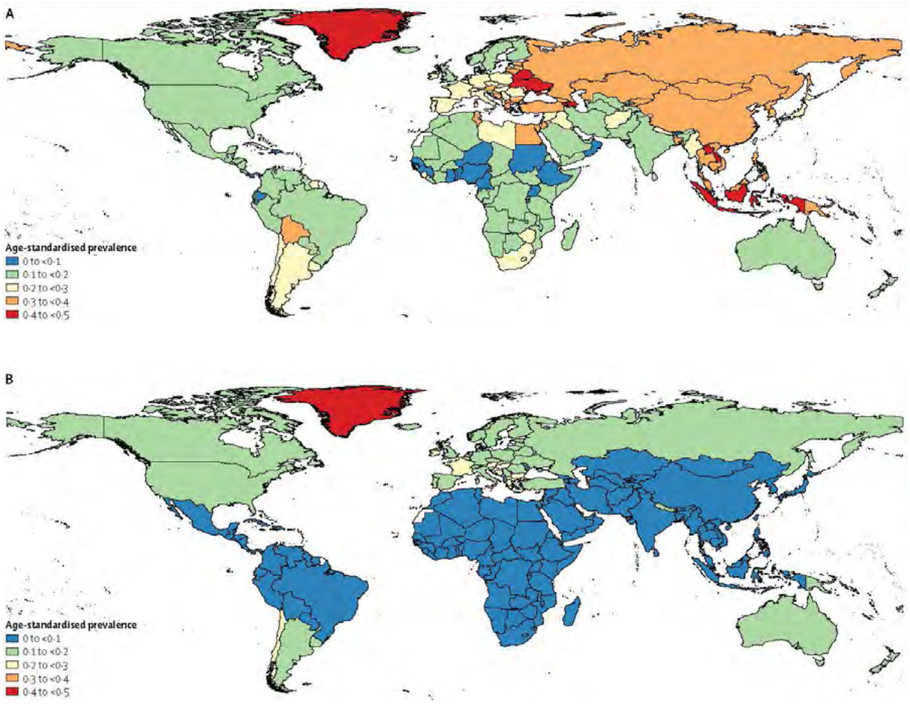


Figure 3: Male and female smoking prevalence globally[11]
Source: Institute for Health Metrics and Evaluation

The data shows that Africa and the Middle East have mixed rates of smoking prevalence, with the highest rates concentrated in North Africa and the Middle East. There is also a large disparity between male and female smoking rates throughout the region. Male smoking dominates, and should be a focus of attention.

However, a great risk is that female smoking will start to rise to European levels, so it is important to ensure that smoking does not start among women as income rises. While Africa and the Middle East may not dominate world smoking, the region is expected to become more prominent over time.

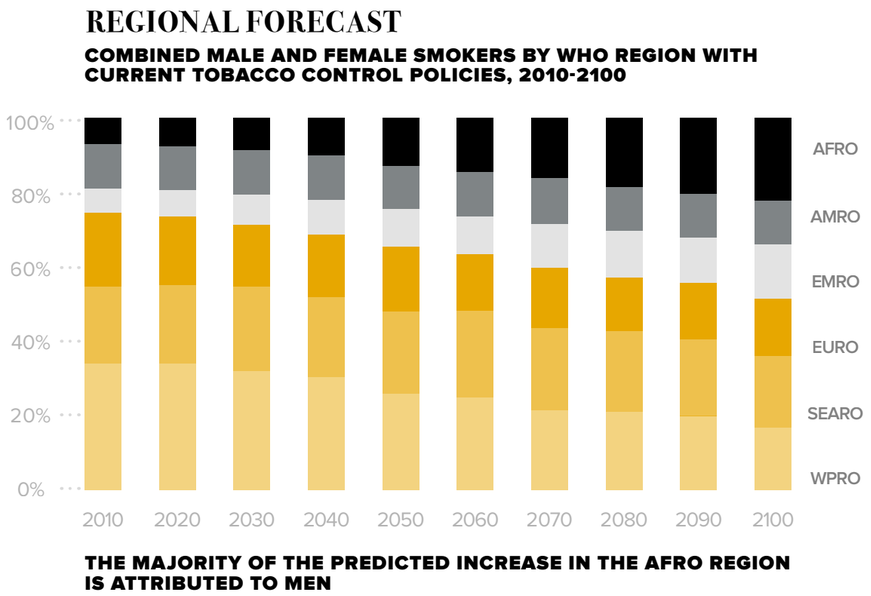


Figure 4: Changing share of smoker population by WHO region 2010-2100
Source: Tobacco Atlas/ WHO 2018 Tobacco Atlas https://tobaccoatlas.org/

The following charts give the best estimates for smoking prevalence in North Africa, the Middle East and Sub-Saharan Africa. To repeat earlier caveats, the quality of underlying data is poor.

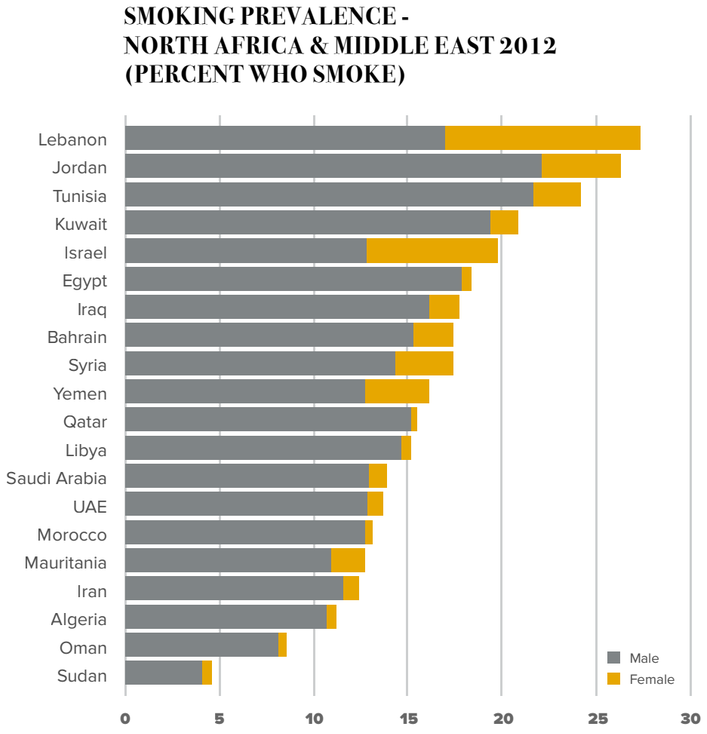


Figure 5: Smoking prevalence in North Africa & Middle East[111]

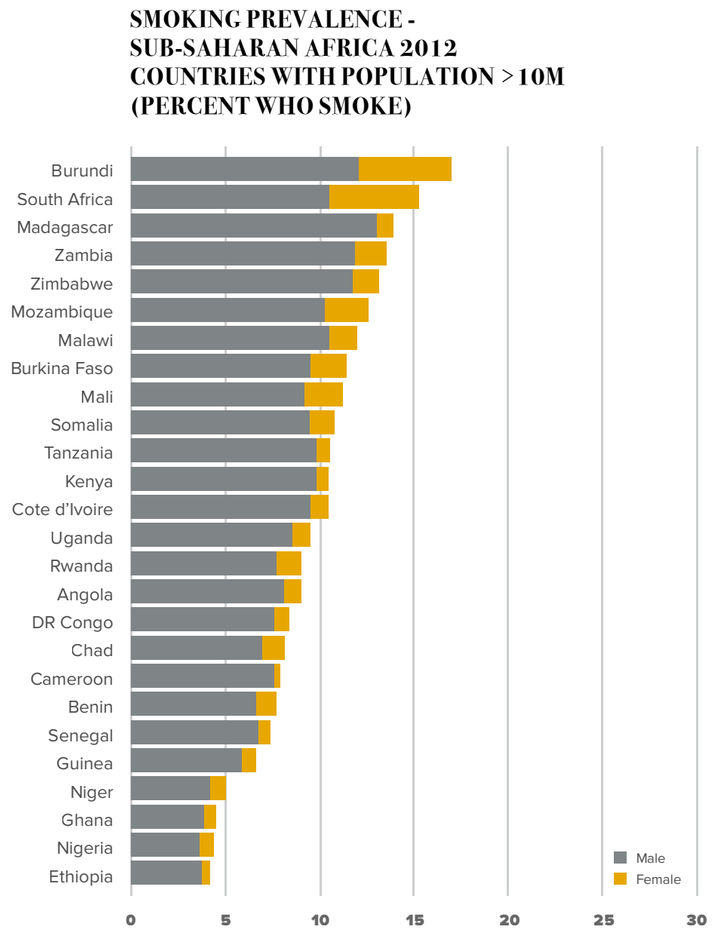


Figure 6: Smoking prevalence in Sub-Saharan Africa[111]

Observations on the patterns of smoking:

- Smoking prevalence is dominated by male smokers in all countries in the region. While the smoking prevalence for the population as a whole is low by international standards, it is high among men. One concern is that smoking among women may begin to rise as male smoking falls – the effect experienced in Europe and United States;
- The rates of smoking are significantly higher in North Africa and the Middle East. However, these states as a bloc have higher disposable incomes. There may, be scope therefore, for the uptake of new technologies and entrepreneurs willing to establish businesses to promote them;
- Most of this data should be regarded as tentative.

NUMBER AND GROWTH OF SMOKERS

We can expand this analysis to see which countries have the greatest number of smokers (i.e. large populations with high smoking prevalence), and therefore where progress in the regulatory regime may have the greatest impact. The chart below shows which countries have the most smokers – a combination of large population and high smoking prevalence.

We can also look at where smoker numbers have been growing at the most rapid rate. The chart below shows which countries have contributed the first 80% of the growth in smokers between 2000 and 2012. Therefore, these are countries with large populations and a growing smoking prevalence.

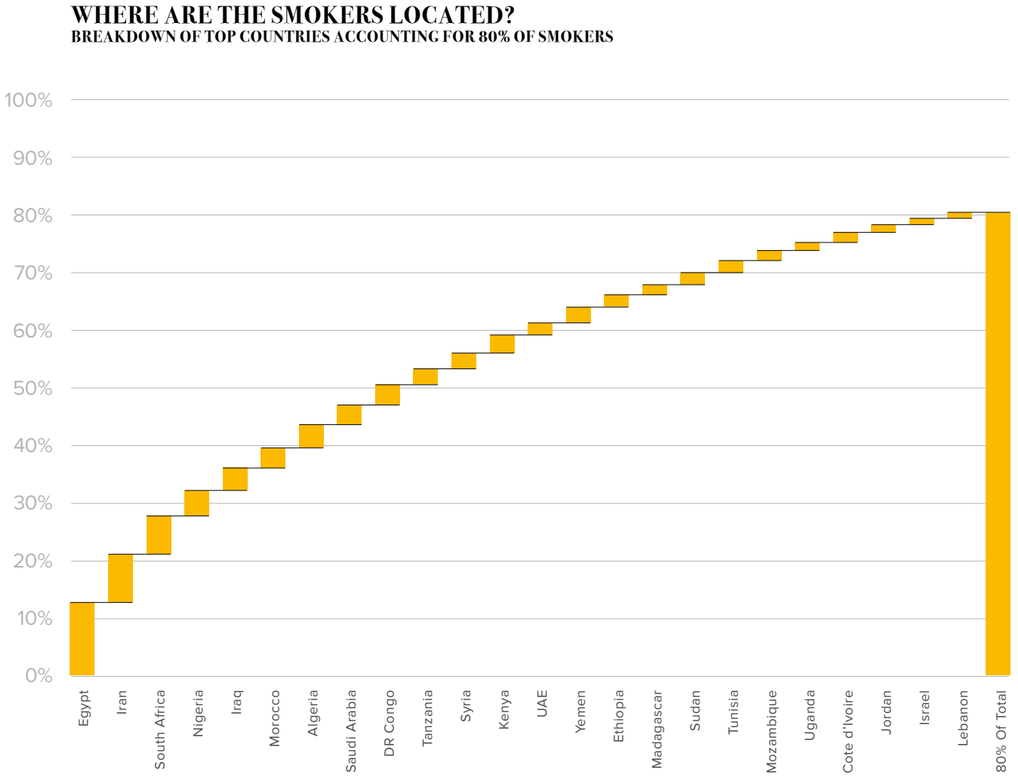


Figure 7: The countries accounting for 80% of Africa & Middle East smokers[111]

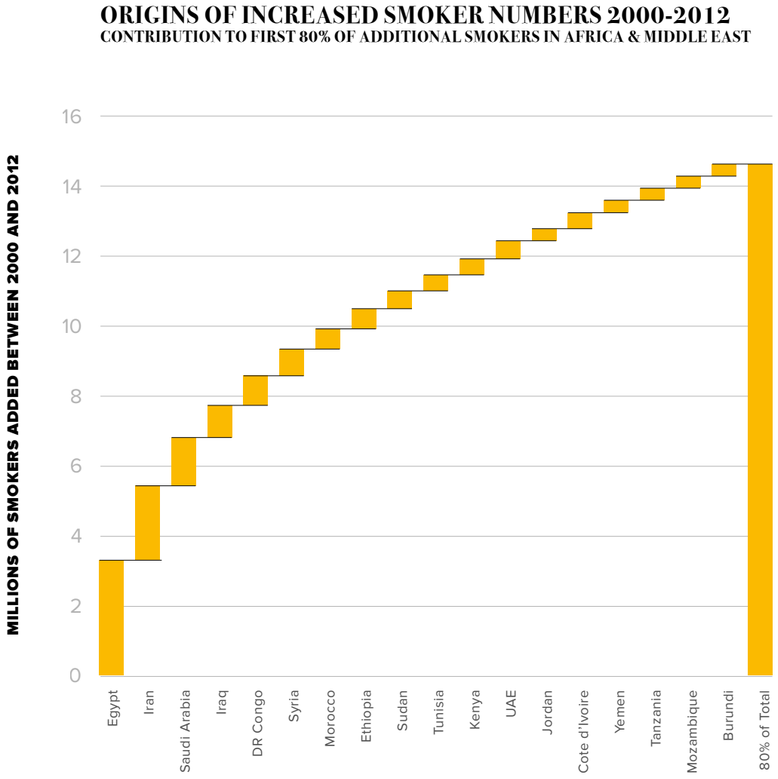


Figure 7: Growth in smoker numbers[111]

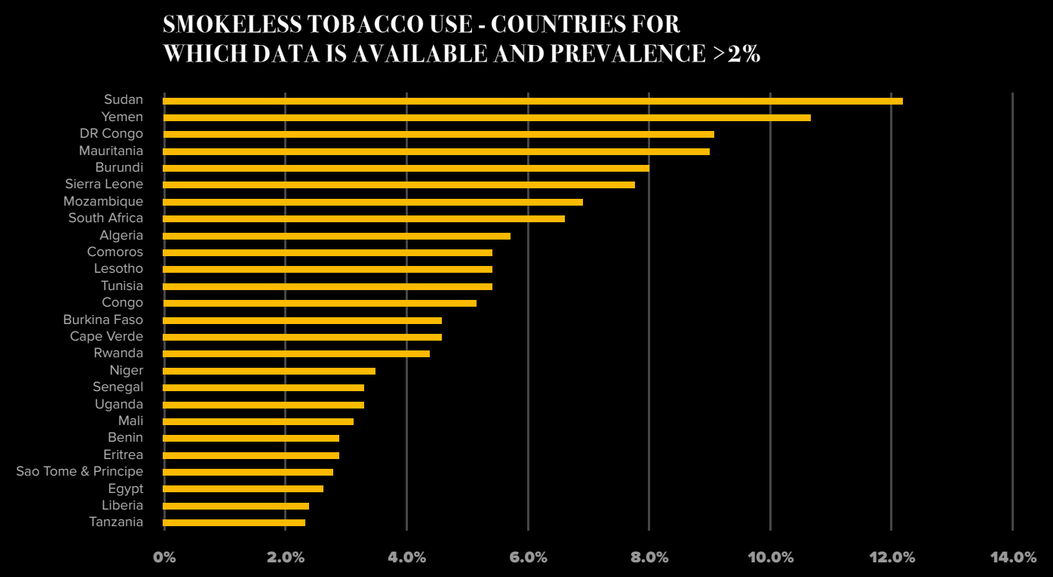


Figure 9: Smokeless tobacco prevalence
Source: Tobacco Atlas / WHO 2018 Tobacco Atlas https://tobaccoatlas.org/

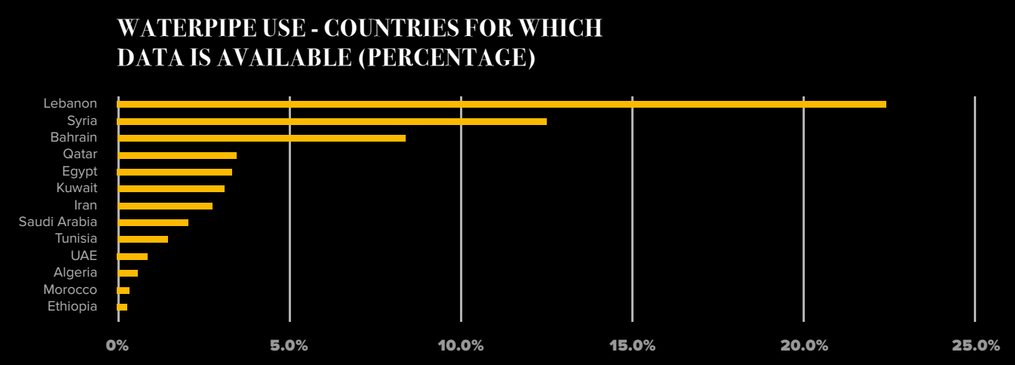


Figure 10: Waterpipe use prevalence
Source: Tobacco Atlas/WHO 2018 Tobacco Atlas https://tobaccoatlas.org/

SMOKELESS TOBACCO

Data on smokeless tobacco use are scarce and of poor quality. Smokeless tobacco use tends to be grounded in tradition and culture, rather than in marketing or modern branding. *(see figure 9)*

Great care is needed in the approach taken to smokeless tobacco in Africa and the Middle East. The danger arises from well-intentioned regulation. If this changes the price, availability or character of smokeless tobacco on the market, there is a danger that users will revert to the cheaper and much more harmful smoking alternatives.

Sudan is a particularly interesting case, as it has the highest rate of smokeless tobacco use (12.1%), but one of the lowest rates of smoking (4.1%). If regulation were used to change the nicotine market in Sudan, there would be a risk of nicotine users shifting from toombak use to cigarette smoking.

However, there are options available to reduce the risks associated with smokeless tobacco use. Since using smokeless tobacco does not involve any chemical transformation through combustion, reductions in risk can be achieved by changing the character of the tobacco used and setting standards for nitrosamines, heavy metals, nitrates etc.

Rather than focus on the risks of smokeless tobacco, it may be wiser to focus on the opportunity that smokeless tobacco presents as a low-cost alternative to smoking.

WATERPIPE USE AND SCIENCE

The data for waterpipe use is also sporadic and of poor quality. The available data show concentrations in North Africa and the Middle East. Waterpipes are also known as hookah, shisha, narghile and several other terms. The WHO has highlighted the prevalence of waterpipe use in its Eastern Mediterranean Region[20]:

> *The Eastern Mediterranean Region (which includes Middle Eastern and North African countries) has the highest prevalence of waterpipe use in the world (9), especially among young people (10, 11). In various Eastern Mediterranean Region countries, the prevalence of waterpipe smoking among children aged 13-15 years ranged from 9% to 15% (12). Furthermore, there is data indicating rapid increases in prevalence; in one longitudinal study of smoking among young people in the Region, the prevalence of waterpipe smoking increased by 40% within 2 years of follow-up (from 13.3% to 18.9%; $p < 0.01$) (13)*

(see figure 10)

There is substantial and growing literature on waterpipes. A PubMed search on papers with "waterpipe" or "hookah" in the title or abstract brings up 690 papers.[21]

The difficulty is drawing this literature into a coherent synthesis and avoiding misinterpretation of findings – for example, inappropriate puff regimes that mimic cigarette smoking rather than actual patterns of waterpipe use.[22]

A WHO expert panel reported on waterpipe health impacts in 2005[23], but this was subject to significant expert challenges.[24] A second, more recent expert report by the WHO[25] outlines the state of evidence and research needs. It summarises the health evidence as follows:

> *"In summary, all the evidence, from studies of molecules to studies of human populations, converges towards the conclusion that waterpipe tobacco smoking causes diseases that are commonly associated with cigarette smoking, including addiction. While there are fewer studies of waterpipe tobacco smoke constituents and their biological activity and health effects than of cigarette smoke, the consistency of the evidence within and across scientific approaches suggests strongly that this basic conclusion will not change as more evidence becomes available. In light of the widespread, growing use of waterpipes worldwide, firm action is necessary and justified to protect public health."*

The research needs are set out on page 42-43 of the report[25] and reproduced in the figure below.

WATERPIPE RESEARCH NEEDS IDENTIFIED BY WHO EXPERT GROUP

- The types and patterns of waterpipe smoking in all regions and cultures;
- The extent to which the chemical and physical properties of the smoke depend on the waterpipe set-up and smoking conditions;
- The epidemiology of waterpipe-associated acute health effects and disease risk. These include addiction, transmission of non-tobacco-related communicable diseases (1), respiratory cancer and cardiovascular and other tobacco-related diseases. The emphasis is on understanding how patterns of use (for example, frequency, ingredients or material placed in the head and/ or the bowl of the waterpipe, group versus individual sessions and whether the mouthpiece is shared) influence disease risk, taking into account specific groups, such as pregnant women and women of reproductive age;
- Development of standardised biomarkers of exposure and effect, such as DNA adducts, in order to obtain complementary evidence of the biological effects of waterpipe smoke on cells and in experimental animals to determine whether waterpipe smoke induces inflammatory and oxidative stress responses;
- The influence of cultural and social practices on initiation and maintenance;
- The relation between smoking waterpipes and other forms of tobacco, including substitution and smoking multiple products, and the extent to which initiation of waterpipe tobacco smoking is a factor in the subsequent use of other forms of tobacco;
- The relation between waterpipe tobacco smoking and use of other drugs, including marijuana;
- Development of culturally relevant prevention and cessation strategies;
- Development of measures for nicotine and tobacco dependence that are validated for waterpipe tobacco smoking, also taking into account differences in culture and language;
- The extent to which flavoured tobacco, waterpipe cafés and other marketing tools, economic factors and the absence of waterpipe-specific tobacco regulation influences the global spread of waterpipe tobacco smoking;
- The effect on non-smokers through the exposure to waterpipe tobacco smoke and smoking, including health effects, and "renormalisation" of tobacco smoking;
- Experimental research on the effects of clinical and public health interventions on preventing and cessation of waterpipe tobacco smoking;
- Whether the use of waterpipes without tobacco or with very low-nicotine tobacco leads to dependence; Epigenomic effects of waterpipe tobacco smoking, such as in the human respiratory epithelia;
- The role of flavours in increased initiation, dual use and the continued use of other tobacco products, as well as long-term effects of flavours; and,
- For the WHO Tobacco Laboratory Network (TobLabNet), an assessment needs to be within two years. This will determine whether the standard operating procedures for measuring nicotine, tobacco-specific nitrosamines and benzo[a]pyrene in cigarette contents and emissions, are applicable or adaptable as appropriate to waterpipe smoke. The assessment follows a request by the WHO during the sixth session of the Conference of the Parties to the WHO FCTC (176).

Figure 11: Research needs for waterpipe use

An abstract of recent systematic literature reviews[26][27][28][29][30] and an expert consensus statement[31] are reproduced below.

Numerous epidemiological accounts suggest that waterpipe smoking (aka hookah, shisha, narghile) has become a global phenomenon, especially among youth. The alarming spread of waterpipe and accumulating evidence of its addictive and harmful effects represent a new threat in the global fight to limit tobacco-related morbidity and mortality. In response to waterpipe's alarming trends, major public health and tobacco control organisations have started, or are considering systematic collection of data about waterpipe smoking to monitor its trends and assess its harmful effects in different societies. Such plans require coordination and agreement on epidemiological measurement tools that reflect the uniqueness of this tobacco use method, and at the same time allow comparison of waterpipe trends across time and place, and with other tobacco use methods.

A decade ago, a group known as the Expert Panel on Waterpipe Assessment in Epidemiological Studies, started working collaboratively to develop standardised measures and definitions for the assessment of waterpipe smoking in epidemiological studies. The group, comprising leading global waterpipe researchers from universities in the Middle East, United States and United Kingdom, worked through an iterative process to develop the suggested instruments and definitions based on current knowledge of the waterpipe epidemic. In a consensus statement, the group states that it has attempted "to expand and update the assessment tools in light of our increased knowledge and understanding of waterpipe use patterns, its context and marketing, as well as the need for evidence-guided policies and regulations to curb its spread." It adds that while the suggested measures are by no means comprehensive, the hope is that they can provide the building blocks for standard and comparable surveillance of waterpipe smoking globally.

Photo by Ramille Soares on Unsplash

E-CIGARETTE AND VAPOUR PRODUCTS – POLICIES IN PLACE

There is still inadequate research and systematic surveillance systems in place for e-cigarette use in Africa and the Middle East. However, there are reports of rising use in some jurisdictions, for example, in South Africa[32] where there has been sufficient trade to justify the creation of the South African Electronic Cigarette Association of South Africa (EASA).

The e-cigarette industry information service, E-cigarette Intelligence, estimates the market in South Africa to be worth US$25m-50m, with a base of 100 000-150 000 active users of e-cigarettes in 2014.[33]

However, there has been some systematic monitoring of policies applied to e-cigarettes. John Hopkins Bloomberg School of Public Health assesses the policy environment in 123 countries.[34] The survey reports the following policies in place (emphasis added for Africa & Middle East states) showing the Gulf States taking an especially hostile approach to e-cigarettes:

*The sale of all types of e-cigarettes is banned in 26 countries: Argentina, **Bahrain**, Brazil, Brunei Darussalam, Cambodia, Colombia, Greece, **Jordan**, **Kuwait**, **Lebanon**, Lithuania, Mauritius, Mexico, Nicaragua, **Oman**, Panama, **Qatar**, **Saudi Arabia**, Seychelles, Singapore, Suriname, Thailand, Turkey, **United Arab Emirates**, Uruguay and Venezuela.*

*A total of 33 countries prohibit or restrict the advertising, promotion or sponsorship of e-cigarettes in their policies. (These are Argentina, Australia, Austria, **Bahrain**, Belgium, Brazil, Canada, Colombia, Costa Rica, Czech Republic, Denmark, Estonia, Fiji, Finland, France, Greece, Hungary, Japan, **Jordan**, **Kuwait**, Mexico, New Zealand, Norway, **Oman**, Panama, Portugal, **Qatar**, **Saudi Arabia**, **Seychelles**, Turkey, **United Arab Emirates**, Uruguay and Venezuela).*

*The use of e-cigarettes is banned in three countries (Cambodia, **Jordan** and the **United Arab Emirates**).*

*The use of e-cigarettes is banned in enclosed public spaces, including bars, restaurants and other workplaces in 15 countries. (These are **Bahrain**, Belgium, Colombia, Croatia, Ecuador, Greece, Honduras, Malta, Nepal, Nicaragua, Panama, Philippines, Republic of Korea, Serbia and Turkey).*

There are also recent moves to ban e-cigarette sales in Uganda[35] and reports of a long-standing ban on e-cigarettes in Egypt.[36] It is unclear how strongly these prohibitions are enforced.

As of 2019, some examples from other selected countries in Africa and the Middle East include the following:

Algeria has no legislation regarding E-Vapour products. E-Vapour products tend to be used more by men than women; the smoking prevalence is also much higher among men.

Cameroon remains one of the countries in the CEMAC (Central African Economic and Monetary Community) zone lacking a national anti-tobacco law according to Euromonitor. The slow implementation and enforcement of anti-smoking laws may lead to the overall increasing cigarette-smoking rate from 7.9% in 2014 to 8.2% in 2019.

Egypt indicates that men account for the largest share of adult smokers of cigarettes with almost 55%. The percentage of female smokers slowly rose from 4.8% in 2014 to 5.5% in 2019. According to a 2018/2019 survey, the awareness of e-vapour products showed as 78% among the respondents. Even though the sales and distribution of these products are banned in the market, consumers are able to purchase them for personal use from foreign websites (Euromonitor country report).

Table 3: Prevalence of cigarette smoking and vaping in Egypt from 2014-2019

COUNTRY	PRODUCT	GENDER	2014	2015	2016	2017	2018	2019
Egypt	Cigarette	Male	55.5	55.4	55.3	55.1	54.9	54.7
		Female	4.8	4.9	5	5.1	5.3	5.5
		Total	30.6	30.6	30.6	30.6	30.6	30.5

Israel has legislated E-Vapour products. The legislation includes prohibiting the sale to minors, not smoking in public areas, and not advertising products in the mass media. Despite these stricter regulations, the retail value of E-Vapour products increased from 3.9 million USD in 2014, to 40.3 million USD in 2019.

Kenya introduced further tax increases on tobacco in 2018, which took its toll as cigarettes registered a decline in retail volume terms, according to Euromonitor. Ongoing efforts by anti-smoking groups are also affecting tobacco sales, with smoking prevalence continuing to decline among both men and women.

Table 4: Prevalence of cigarette smoking and vaping in Kenya from 2014-2019

COUNTRY	PRODUCT	GENDER	2014	2015	2016	2017	2018	2019
Kenya	Cigarette	Male	21.6	21.5	21.4	21.4	21.2	21.2
		Female	1.7	1.6	1.6	1.6	1.5	1.5
		Total	11.5	11.4	11.3	11.3	11.2	11.1

Morocco permits the use of E-Vapour products in public places and they are not subject to any restriction. According to Euromonitor, most vapours shops have closed in Morocco due to low demand of their products and components. In addition, smokers are more willing to use traditional smoking products because of the lower price.

Nigeria implemented the second of three annual increases in specific taxation, which resulted in an ongoing rise in the unit prices of cigarettes. As higher prices hit consumers, retail volume sales of cigarettes therefore saw a decline in 2019. In 2019, the higher prices of cigarettes partially drove a continued decreasing trend in smoking prevalence over the review period.

Saudi Arabia permits the use and selling[37] of e-vapour products, but there is no legal way for consumers to purchase a vape module, vape juice or any of the equipment needed to vape.

South Africa has an under regulation of e-vapour products. In recent years, the sales value of E-Vapour and heated tobacco has been increasing, while the sales of combustible cigarettes have showed a declining trend. The prevalence of vaping increased slowly from 2014 to 2019, as the cigarette-smoking rate declined.

Table 5: Prevalence of cigarette smoking and vaping in South Africa from 2014-2019

COUNTRY	PRODUCT	2014	2015	2016	2017	2018	2019
South Africa	Cigarette	19	18.7	18.6	18.5	18.9	18.4
	E-Vapour	0.2	0.3	0.3	0.3	0.4	0.5

Tunisia has seen an increase in the cigarette smoking prevalence, from 31.8% to 32.6% from 2016 to 2019. The rate is extremely high among males, reaching 55.1% in 2019.

Despite the gender gap between male smokers and female smokers, the smoking prevalence among females is higher than that in most other countries in Middle East and Africa.

Table 6: Prevalence of cigarette smoking in Tunisia from 2014-2019

COUNTRY	PRODUCT	GENDER	2014	2015	2016	2017	2018	2019
Tunisia	Cigarette	Male	55.2	54.5	54	54.1	54.4	55.1
		Female	10.6	10.7	10.7	10.7	11	11.1
		Total	32.4	32	31.8	31.9	32.1	32.6

The United Arab Emirates has developed a national indicator of the smoking rate, which remained at 16.4% of the adult population in 2019, according to Euromonitor. The UAE is currently following plans to reduce smoking prevalence to 15.7% of the adult population by 2021. The country has formed a national committee for tobacco control comprising 12 government entities. This committee is tasked with drafting tobacco control-related legislations, regulations and systems, along with a database on tobacco use, its products and its trade. The country's efforts in this respect have reportedly yielded an 18% decrease in the rate of adult smokers since 2010, in accordance with the aims of the health survey 2017/2018. In addition, it has imposed a 50-100% selective tax on tobacco and its derivatives.

Photo by Gift Habeshaw on Unsplash

TOBACCO CONTROL STRATEGY

Policymakers have been working for five decades to control the burden of tobacco-related diseases. The tobacco control strategy should focus on reducing premature death and serious harms like cancer, cardiovascular and respiratory disease as rapidly as possible. To that end, the most effective tobacco control strategy has four main elements:

1. To provide strong incentives not to start smoking;
2. To motivate and help people to quit smoking;
3. To reduce harm to non-smokers arising from exposure to toxins in second hand smoke; and
4. To reduce harm to those who continue to use nicotine.

THE CONVENTIONAL TOBACCO CONTROL POLICY APPROACH – MPOWER

A well-established package of tobacco control measures aims to change the demand for tobacco products by implementing the first three elements of tobacco control discussed earlier. The World Health Organization and other organisations occasionally use the acronym MPOWER to describe this package.[38]

MPOWER has six components:

M onitor tobacco use and prevention policies
P rotect people from tobacco smoke
O ffer help to quit tobacco use
W arn about the dangers of tobacco
E nforce bans on tobacco advertising,
R promotion and sponsorship
aise taxes on tobacco

These measures have contributed to a decline in smoking in developed countries from very high levels in the 1950s-1980s. They also form the basis of the WHO's Framework Convention on Tobacco Control[39], which aims to develop these measures more robustly in developing countries.

Although effective, these measures are subject to implementation resource constraints, enforcement burdens and more subtle political limitations. They include how much the state should intrude in personal choices, whether smoking bans can be justified in private spaces such as homes and concern about tobacco taxes being regressive or creating black markets. Each country addresses these issues differently.

THE MISSING POLICY APPROACH – TOBACCO HARM REDUCTION

Harm reduction, the fourth strand in the tobacco control strategy outlined above, has received less attention and has evoked hostility from some tobacco control activists. It has been argued that this is due to confusion about the goals of tobacco policy[40] – whether they are directed at reducing disease, reducing tobacco use, reducing nicotine use or destroying the tobacco industry.

This confusion matters because these goals may be in conflict in cases where nicotine products offer much lower disease risk than smoking.

THE TOBACCO HARM REDUCTION APPROACH

The fourth strand of tobacco control strategy is tobacco harm reduction. The WHO Framework Convention on Tobacco Control (Article 1) explicitly endorses harm reduction strategies in tobacco control[39]:

> *(d) "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).*

This means reducing harm to people who continue to use nicotine or tobacco. Despite this endorsement in the text of Framework Convention for Tobacco Control (FCTC) itself, this approach has not yet been developed in the Convention. It has also not been widely developed as a tobacco control strategy other than by chance.

Tobacco harm reduction remains controversial[41][42], but there is mounting evidence that it could be transformative in reducing the burden of disease, and many scientists now recognise the opportunity to achieve rapid reductions in disease risk.[43]

Photo by Charles Etoroma on Unsplash

THE KEY TOBACCO HARM REDUCTION INSIGHT

A key insight into tobacco and health strategy is to recognise the ultimate cause of harm. Nicotine is the active drug in tobacco, and the reason why people smoke tobacco. However, nicotine is not the primary cause of harm arising from smoking. For four decades, it has been understood that[44]:

People smoke for the nicotine but die from the tar

Nicotine is not a cause of cancer, cardiovascular disease or the respiratory conditions that dominate the ill health from smoking.[45] For example, in England in 2013, smoking caused 79 700 deaths of which 37 200 were from cancer, 24 300 from respiratory diseases, 17 300 from circulatory diseases, and 900 from digestive diseases. No deaths have been attributed to pure nicotine use.

Pure nicotine is not completely benign, but it is widely sold in medicinal form and does not cause any serious illness.[46] Many decades of experience with Swedish snus (a form of smokeless tobacco) suggests that tobacco and nicotine use can carry a very low risk when there is no combustion.[16] The US Surgeon General has made a detailed assessment of nicotine risks[47], and though it is possible to measure many effects on the body, these are trivial compared to the harms clearly associated with smoking.

This insight opens up the prospect of "tobacco harm reduction" – a way to use the mildly psychoactive drug nicotine, without the major health consequences of exposure to tobacco smoke.

This relies on technologies that deliver nicotine without smoke – or what are known as "alternative nicotine delivery systems" (ANDS). A growing range of technologies can provide an acceptable or satisfying dose of nicotine without combustion. These alternative nicotine delivery systems (ANDS) are evolving rapidly, partly because advances in battery technology provide high power and energy density in a compact form that works in consumer products.

There are also more traditional ANDS, such as smokeless tobacco, which can be made at high standards that remove nearly all health risk. ANDS include vapour products, nicotine inhalers, heated tobacco products, smokeless tobacco products and novel nicotine products delivered through the oral mucosa.

THE PUBLIC HEALTH CASE FOR TOBACCO HARM REDUCTION

The public health proposition is that:

1. ANDS can provide a satisfactory alternative to smoking (nicotine, sensory and ritual aspects) and will displace cigarette use in the consumer market for recreational nicotine.

2. ANDS can dramatically reduce risks to health, likely by 95-100%, among those who switch with negligible impact on bystanders, at lower cost, and with lower social stigma. The vast majority of harm in smoking comes from tar and hot gases – products of combustion, rather than nicotine. These are almost entirely absent in e-cigarette vapour.

3. ANDS are market-based public health phenomena that "meet people where they are". The public health benefit does not rely on public spending, coercion, prohibition, punitive taxes, fear, stigma or treating smokers as though they are ill. The fact that government funding and resources are not required should be a significant advantage in countries with tight budgets and many competing priorities.

4. The risks of harmful unintended consequences, like gateways to smoking, are low. They remain hypothetical and are unsupported by any previous evidence.

EVIDENCE THAT ALTERNATIVE NICOTINE DELIVERY SYSTEMS ARE MUCH SAFER THAN SMOKING

The basic argument, common to all the ANDS products, is that they do not involve combustion processes, and the products of combustion of organic material (the tobacco leaf) do most of the damage.

Vapour products

The most important difference between cigarette smoking and e-cigarette use (sometimes called "vaping") is the dramatically lower health risk to the user. While it is impossible to go forward in time by several decades and look at what harm, if any, is caused by e-cigarettes, we still know a great deal about the likely risks of vaping compared to smoking.

Measurements of toxic constituents of cigarette smoke and e-cigarettes suggest e-cigarette users will experience much lower toxic exposures than smokers will, and this is a reasonable proxy for a health risk. Most of the toxic agents thought to cause harm from cigarette smoking are either not present in e-liquid vapour or present at significantly lower levels.

Major reviews of e-cigarette safety[46][48][49] give confidence that risks are likely to be at least 95% lower than smoking – a view recently endorsed by the government agency Public Health England.[50][51] At present, there is no evidence suggesting that e-cigarettes are a cause of any serious disease, so even the 5% residual risk is an allowance for unknowns. The most recent authoritative statement is from the Royal College of Physicians[52]:

> *"Although it is not possible to precisely quantify the long-term health risks associated with e-cigarettes, the available data suggests that they are unlikely to exceed 5% of those associated with smoked tobacco products and may well be substantially lower than this figure." (Section 5.5 Page 87)*

Smokeless tobacco

Different forms of smokeless tobacco pose different degrees of risk. Swedish snus has been studied extensively over many decades and appears to pose minimal or no material risk.[16]

However, in developing countries, a broad review of smokeless tobacco showed a wide range of potentially hazardous agents in products used in these countries, with particularly high levels of carcinogenic nitrosamines found in Sudanese toombak.[53] The National Cancer Institute has compiled information on smokeless tobacco use in different regions of the world; including chapters on Africa and the Middle East.[54]

Even the most harmful forms of smokeless tobacco are likely to be much less dangerous than smoking, given the wide range of hazardous agents in cigarette smoke that are drawn into the lungs. No equivalents exist for smokeless tobacco users for most of the exposures that smokers face. Expert advisers to the WHO have recognised this range of risks within the smokeless category and have advocated a systematic regulatory approach to reducing these risks.[55]

Heated tobacco products

These products have only recently appeared on the market in a form acceptable to consumers. Tobacco manufacturers that make the products have conducted most of the research on them and they have not been assessed independently. However, recognising that caveat and being duly cautious, the products do appear to offer the promise of very substantially reduced risk while mimicking cigarette smoking more closely.

THE EXPERIENCE OF E-CIGARETTE USERS

Although there is good science to underpin confidence in e-cigarettes, it is also important to consider the human experience. For example, the human stories from Australia[56], the United Kingdom[57] and the United States[58] help to explain why and how the products work. Here are three examples of thousands of user testimonials in their own words:

Example of experience from Australia

"It's really hard to believe it's been a year. Never in my wildest dreams did I think that I could really quit smoking and make it last this long. I figured my addiction would kill me one day. Now, I am in great health, have managed to slim down to what I weighed in my 20s, and am fitter than I have been in years. I've tried to convert many people, but so far have only succeeded with one friend. I hope to continue to pay forward the time that the Brisbane lady gave me at the airport one year ago and will chat to anyone in the street about vaping."

Example of experience from the UK

"Vaping has probably saved my wife's and my own life, I was a smoker for 50 years, nothing I have ever tried has had the impact of vaping, this alone was the only thing that saved me, how can governments legislate against something that is saving so many people's lives?"

Example of experience from the United States

"I had been a pack-and-a-half a day smoker for 25 years, the majority of my life. I had tried to quit for about a third of that, using methods like the gums, but without success – I could only ever quit for a few days at most. In December of 2014, I first tried vaping, exploring a variety vaporizers and fluids. I cut my smoking down dramatically and was a duel user for about a month and a half. On my birthday in the following January, I threw my cigarettes away by plan, and have been an EX-smoker for the many months since then."

With thousands of similar testimonies, any government official or minister has to consider what reason they would intervene to prevent experiences like this. We should encourage similar experiences in Africa and the Middle East, as there is no reason for governments to place obstacles in the way of smokers making the life-saving transformations described in these testimonials.

THE GOVERNMENT CASE FOR LEGAL REGULATED SALE OF LOW RISK NICOTINE PRODUCTS

Policymakers must base decisions with real-world life-or-death consequences on a dispassionate view of the evidence, and the scientific evidence now suggests that alternative nicotine delivery systems (ANDS) could benefit millions of smokers.

- Smokers who switch to ANDS are likely to avoid at least 95% of the major smoking-related risks for cancer, heart disease and respiratory illness. They will also experience significant short-term gains in health and wellbeing and may be financially better off. No government should deliberately try to deny smokers this option, which millions of smokers worldwide have now adopted.
- E-cigarettes are an effective tool for switching from smoking at zero cost to the public purse, since the individual smokers bear the costs.
- Advances in scientific understanding of the opportunities to use ANDS show that a "tobacco harm reduction" strategy could secure large health gains by enabling smokers to switch to much lower risk products. E-cigarettes are at least as effective as medical smoking cessation approaches (such as NRT or behavioural advice), but they are far more acceptable and popular, hence they will have a far wider reach than medical treatments
- A widespread switch to ANDS would reduce exposure to second-hand tobacco smoke. E-cigarettes pose no material risk to bystanders.
- The quality of products available from reputable manufacturers is now very high and they are on widespread sale in the European Union, North America and throughout Asia without any major problems. Many smokers report success at quitting smoking and better health as a result.
- There is a growing international experience with the regulation of ANDS as consumer products.
- It would be better for a region to have its own legitimate and properly regulated supply chain and to have responsible producers contributing corporate and sales taxes as appropriate.
- There is no indication anywhere in the world that ANDS undermine tobacco control, induce young people to smoke, or reduce the rate that adults quit smoking. The evidence, when examined dispassionately, shows what a neutral observer would expect unless presented with evidence to the contrary; people use much safer products to reduce their health risks or quit smoking.

Poor media reporting and misrepresentation of scientific findings have exaggerated risks, but understated the benefits of e-cigarettes. There are no precedents for banning safer products while leaving the most dangerous products widely available. On the contrary, ANDS will support a tobacco control agenda by giving smokers options to respond to increasing taxes and other controls on smoking. ANDS offer far better options to smokers than switching to shisha or buying cigarettes on the black market.

"Poor media reporting and misrepresentation of scientific findings have exaggerated risks, but understated the benefits of e-cigarettes."

ARGUMENTS AGAINST PROHIBITION OF E-CIGARETTES

Several jurisdictions, notably the Gulf States and Egypt, have considered or implemented outright or de facto prohibitions on vapour products. It is a highly unusual and grave step for a government to ban a product far safer than the dominant and widely available product and thereby to deny that option to smokers. It is essential to undertake an in-depth examination of the ethics of such a decision.

Professor Wayne Hall and colleagues outlined the key ethical arguments against prohibiting Electronic Delivery Systems (ENDS) such as e-cigarettes[59], stressing the following four principles (with our explanations):

1. **Respect for autonomy** – why should the government prevent citizens from making these choices for themselves? Governments do not intervene to prevent most choices people make about risk, e.g. playing contact sports, consuming alcohol and even smoking itself.

2. **First do-no-harm ("non-malificence") principle** – is the government confident that a prohibition will achieve its aims and do this with minimum harm? Prohibitions may have severe unintended consequences including a black market, unregulated products, criminal networks, reducing the number of smokers who quit and distorting the legal market to favour cigarettes.

3. **Denying benefits ("beneficence principle")** – how can the government justify denying smokers the option to switch to a much lower risk product, which may save them from a serious disease?

4. **Distributive justice** – smoking is often concentrated in poor groups in society and may be rising in poorer countries. The future evolution of disease and mortality may aggravate inequality between and within countries, but ENDS may be a cost-effective way to reduce these inequalities without requiring public spending or laws that are difficult to enforce.

The World Health Organization was careful in its 2014 briefing on ENDS[60] to avoid proposing prohibitions on ENDS. Instead, the WHO stressed regulation rather than prohibition:

> *ENDS, therefore, represent an evolving frontier, filled with promise and threat for tobacco control. Whether ENDS fulfil the promise or the threat depends on a complex and dynamic interplay among the industries marketing ENDS (independent makers and tobacco companies), consumers, regulators, policy-makers, practitioners, scientists, and advocates. (1)*

The citation (1) at the end of this specific WHO statement refers to a commentary by Dr David Abrams, Executive Director of the Schroeder Institute for Tobacco Research and Policy Studies, and Professor in the Department of Health, Behaviour and Society at the Johns Hopkins Bloomberg School of Public Health. Writing in JAMA, Abrams[41] concludes:

> *The more appealing e-cigarette innovations become, the more likely they will be a disruptive technology. Although the science is insufficient to reach firm conclusions on some issues, e-cigarettes, with prudent tobacco control regulations, do have the potential to make the combusting of tobacco obsolete. Strong regulatory science research is needed to inform policy. If e-cigarettes represent the new frontier, tobacco control experts must be open to new strategies. Statements based on ideology and insufficient evidence could prevent the use of this opportunity before it becomes established as part of harm reduction strategy.*

It is clear that the leading edge in tobacco control is not in prohibition of these products, but in working out how best to exploit the major opportunities while minimising any residual risks. In other words, tobacco control leadership means skilful design of regulation based on sound science and understanding of smokers' behaviour, not on ideological objections to nicotine use.

THE VISION: THE ENDGAME FOR TOBACCO RELATED DISEASES

THE POTENTIAL TO DISRUPT THE MARKET FOR TOBACCO

The $800 billion global market for cigarettes is the only thing really threatened by ANDS. To prohibit or over-regulate ANDS when they compete with cigarettes but have far lower risk to the user would be an unscientific, unethical and a lethal error based on current evidence.

Dr Derek Yach, former WHO Director for the tobacco policy-led development of the global Framework Convention on Tobacco Control, summarises this perspective[61]:

> *At the moment, it's estimated that there will be a billion tobacco-related deaths before 2100. That is a dreadful prospect. E-cigs and other nicotine-delivery devices such as vaping pipes offer us the chance to reduce that total. All of us involved in tobacco control need to keep that prize in mind as we redouble efforts to make up for 50 years of ignoring the simple reality that smoking kills and nicotine does not.*

The science shows that Dr Yach is correct in this assessment and that the opportunities from e-cigarettes far outweigh any conceivable risks. The main risks in relation to e-cigarettes arise from excessively restrictive policy positions or prohibition: these will have the effect of causing more smoking, ill health and unhappiness than would be otherwise.

THE ENDGAME FOR SMOKING RELATED DISEASES

There is a vibrant debate about what policies might be required to bring about the end of smoking or tobacco use. A special supplement of the Tobacco Control Journal was devoted to the subject[62] and the ideas have been subject to intense criticism.[63] Here are some of the key issues:

Summarising the policy challenge. The main challenge for governments is to find a proportionate way of regulating these products that will exploit the huge public health opportunity and minimise any risk to non-smokers or children, but avoid the unintended effect of protecting the cigarette trade from competition, blocking valuable innovation or denying/ obstructing smokers from access to much safer smoking alternatives.

Beyond "harm reduction". To call such a vision "harm reduction" is to belittle this pioneering technological progress in the recreational nicotine market. For centuries, humans have used ingenuity to solve problems and through emergence and uptake of superior technologies, this vision brings about the obsolescence or marginalisation of a harmful and polluting way of using nicotine.

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ANNEX

Preferred Regulatory Frameworks for Alternative Nicotine Systems in Africa and The Middle East

THE OBJECTIVES OF E-CIGARETTE REGULATION

E-cigarette regulation should focus on:

- Ensuring that e-cigarettes and vapour products are as safe as possible without compromising their appeal as alternatives to smoking; and
- Making certain they are not marketed in a way that increases total population harm, including through recruitment of young people or non-smokers who would not otherwise smoke.

Note that the aim should not be to prevent all young people from using e-cigarettes. There may be a significant health benefit in young people using e-cigarettes if this is an alternative to smoking or other harmful behaviour.

The aim of regulators should be to achieve a "sweet spot" of regulatory intervention that builds confidence among consumers and removes rogue operators and defective products from the market. However, it should, not impose costs, burdens and restrictions that crush the smaller players radically change the products available and obstruct innovation.

The graphic below illustrates the concept of this relationship.

CONSUMER VALUE FROM E-CIGARETTE REGULATION (CONCEPTUAL)

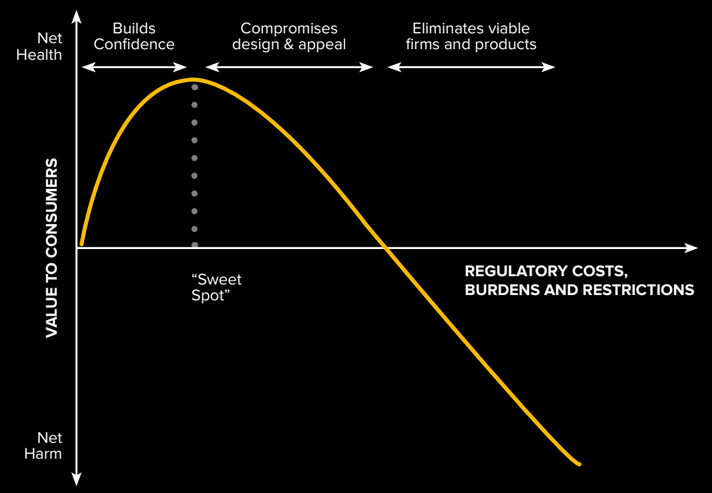

Figure 1: Optimum regulation of alternative nicotine delivery systems

The optimum regulatory regime would strike a subtle balance between protecting users, non-users, bystanders, and limiting the risks of harmful unintended consequences.

POOR REGULATION IS THE PRIMARY RISK TO PUBLIC HEALTH

The primary risk to the otherwise highly positive developments with e-cigarettes is poor and excessive regulation. At the heart of the regulatory challenge is a "double negative" – being tough on e-cigarettes is being tough on the competitive alternative to cigarettes.

There is a danger that loss-averse regulators and officials will place excessive focus on the residual risks associated with vapour products, but in doing so, render them less effective and appealing as alternatives to smoking. In doing so, they will actually increase total health risks through the unintended consequence of additionally continuing smoking.

This weakness is present in all regulatory proposals advanced so far.

REGULATORY OPTIONS

As a special category of consumer products, alternative nicotine delivery systems (ANDS) and require a customised regulatory framework. There is no reason to regulate these products as something they are not – as tobacco products, poisons or medicines.

REGULATION AS A POISON

There is no case to apply poisons legislation to e-cigarettes or e-liquids. This is because the nicotine concentrations used in retail devices and liquids (0-3.6%) do not present a significant hazard that cannot be addressed with the same approach as any other chemical present in the home.

As an example, UK legislation sets a 7.2% (72mg/ml) threshold for definition of nicotine liquids as poisons – primarily for use as pesticides. These liquids on sale typically contain between 0-3.5% nicotine.

REGULATION AS MEDICINES

There is no case to regulate ANDS as medicines, quite simply, because they are not medicines. The application involved in regulating medicines is a highly expensive and burdensome regime. Its effect would be to provide regulatory protection to the cigarette trade and favour large tobacco companies in the e-cigarette market.[1] In addition, this move would:

- Create barriers to entry that would exclude most firms and products on the market that consumers are already using successfully as alternatives to smoking;
- Favour the tobacco industry's products, allowing tobacco companies to cross-subsidise compliance from cigarette sales;
- Raise costs, impose burdens and place limitations on products that serve no useful purpose;
- Form a de facto protection of the incumbent product – cigarettes; and
- Possibly be unlawful if e-cigarettes do not match the definition of a medicine in medicines legislation. Courts in several countries including the United States, Sweden, Germany and Estonia have already rejected the mandatory designation of e-cigarettes as medicines under their respective medicine frameworks.

For these reasons, the European Union legislature rejected the approach of using mandatory medicines regulation in 2013.[2]

REGULATION AS TOBACCO PRODUCTS

Regulating e-cigarettes in the same way as cigarettes are a basic error of analogy, for two reasons:

1. In terms of harm to human health, the products are completely different. The risk of vaping is likely to be at least 95% lower than that of smoking and it may prove to have no material risk at all.

2. Cigarette regulators would aim to deter all use. In the case of e-cigarettes, there is a good case to encourage smokers or potential smokers to vape instead, especially if they are unwilling or unable to quit smoking nicotine completely.

Applying tobacco product regulation to e-cigarettes – for example, by banning advertising or imposing excessively large and bold warnings – could easily result in a de facto protection of the cigarette trade. Many elements of the EU Tobacco Product Directive Article 20 on e-cigarettes borrow from tobacco regulation, but disproportionately damage the e-cigarette business model compared to cigarettes.

REGULATION AS CONSUMER PRODUCTS

ANDS are marketed and purchased as recreational consumer products – as alternatives to smoking. This is the appropriate regulatory approach. General consumer regulation should apply for e-liquids and vaping devices, with some specific technical quality control standards, defined labelling requirements, enhanced marketing controls that reflect the adult nature of the product and proper communication of risks and benefits.

The appropriate model is the one that most closely reflects reality, namely, regulation designed for a consumer product with additional specific features.

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APPENDIX D

Tobacco Harm Reduction (THR) Advocacy Guide and Objection Handler

SECTION 1
Elements of a THR Advocacy Campaign

SECTION 2
Talking with Policymakers

SECTION 3
Objection Handler: Common Questions and Answers concerning THR, specifically Vaping Products

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ABOUT THE GUIDE

Tobacco Harm Reduction (THR) can prevent tobacco-related disease and premature deaths. That is why it is essential to change public health policy, to include this lifesaving measure. However, there is tremendous opposition to THR, mostly from activist tobacco control groups, who refuse to see THR as complementary to tobacco control.

Therefore, well-planned strategic advocacy campaigns are needed in all UN member states to make THR a reality, in addition to strengthening tobacco control. This guide is designed to help health professionals, NGOs and civil society organisations plan and conduct effective advocacy campaigns so that robust, evidence-based THR-friendly health policies can be adopted and implemented.

HOW TO USE THE GUIDE

This guide provides a snapshot of elements needed to build a successful advocacy campaign. Additional tools are available on:
www.ahra.co.za & **www.tobaccoharmreduction.net**
as an open knowledge, referenced repository for all stakeholders interested in preventing tobacco-related disease and premature death.

ACKNOWLEDGEMENT

Material for this repository has been sourced from publicly available information and referenced where possible.

SECTION 1: ELEMENTS OF AN ADVOCACY CAMPAIGN

GENERAL ADVOCACY STRATEGY TEMPLATE

OBJECTIVES
Determine the objectives relating to tobacco harm reduction strategies, policies, practice, and products in targeted cities, regions and countries.

KEY DECISION-MAKERS (TARGET AUDIENCES)
Formal institutions that can make this possible:
- Government (Usually the Ministries of Health, Finance or the Medicines Regulatory);
- Agencies such as the Food and Drug Administration;
- WHO Director-General and Leadership; and
- Public health community, notably health professionals.

KEY INFLUENCERS
Role players that can help influence formal institutions to make the right decision:
- Key opinion leaders (scientific and public);
- Consumer groups;
- Public media;
- Specialised media, e.g. leading health journals; and
- Health professional associations.

KEY MESSAGE(S)
For tobacco harm reduction, it is essential to emphasise the BENEFITS such as the prevention of tobacco-related disease and premature death in all key messaging.
- Highlight every way in which non-combustible, nicotine-based products can save lives and prevent combustible tobacco-related disease and disability; and
- Stress the relative safety of nicotine in comparison with combustible tobacco.

MESSENGERS
- Identify and empower credible third-party experts or expert groups; and
- Identify and persuade opinion leaders with sound evidence.

DELIVERY
Deliver key THR messages at the appropriate time, initially using quiet diplomacy. Thereafter, transform messaging communication into transparent campaigns and open scientific debate as soon as possible. Take note that science is on the side of tobacco harm reduction advocates. Expect those tobacco control activists that attack tobacco harm reduction usually do so by trying to discredit the messengers, and rarely the message – that THR can save lives. Expect and understand these actions and do not let them deter you in efforts to save lives.

ADDITIONAL ADVOCACY METHODS
Formal institutions that can make this possible:
- Strategic research, e.g. testing awareness of harm reduction and its potential benefits;
- Customised publications that can increase awareness of THR;
- E-media – elicit the involvement of bloggers (especially those that specialise in health and medicine) by quoting reputable scientific evidence and demanding that policy be based on sound evidence.

CONTINGENCY PLANNING AND ALTERNATIVE STRATEGIES
There is a likelihood that the tobacco harm reduction advocacy projects and their associated groups or individuals will be attacked. Contingency plans will be set up to manage this eventuality.

Aside from the pillars of tobacco control mentioned elsewhere in this book, these basic principles of advocacy are useful in raising awareness of the benefits of tobacco harm reduction. Other important steps to follow in THR advocacy include:

1 Fact finding

Before starting a THR advocacy campaign, try to gather relevant local background information. For example, individuals in other countries are weary of information from the Royal College of Physicians. They are interested in local prevalence data and relevant research. When gathering facts, make sure to know about the latest science and evidence in support of THR, current laws and regulations and what gaps may exist. Also examine any past advocacy efforts on the same issue, to establish which strategies worked and which were unsuccessful.

2 Set clear policy objectives

As with any successful project or campaign, the objectives should be clearly enunciated and be specific, measurable, achievable, relevant and time bound. Use the advocacy template above to identify your goals clearly. Most importantly, make sure you know who or what leadership structure can make a decision to facilitate THR policy in your region or country.

3 Build strong alliances, coalitions and partnerships

Before starting an advocacy campaign, identify and build coalitions or partnerships. Working in coalition or partnership with others is the best way to generate momentum and 'background noise' to demonstrate support for your issue. You are more likely to be successful if you can identify a 'few good persons or groups' to form the core group and drive the campaign forward.

4 Identify and train public spokespersons

You will improve your chances of campaign success if you are able to identify a publicly active, credible scientist that can speak independently and passionately about the evidence base and benefits of THR. Such spokespersons are not only found in the health and medical sectors, so be sure to also investigate consumer groups, civil society and professional or business groups in the fields of health, education, economics and science. If possible, use media training to help such individuals be more effective spokespersons for the THR cause.

5 Prepare draft policy arguments/ use appropriate language

Campaigners often come across as whiners. They are passionate, loud and think that shouting louder will eventually get them heard. In general, policymakers know that these types of advocate are ineffective as they pose no threat once the storm dies down. However, advocates that do their homework, uncover the supporting science and start drafting what preferred policies should look like, will ensure that policymakers take notice. Some argue that there should be 'no interference of the policymaking process'. However, this view is uninformed and naïve. Democratic societies should encourage debate and science-based policies should be the norm.

For example, the United Nations (UN) – in its efforts to combat non-communicable diseases linked to tobacco and alcohol – has repeatedly called for 'whole-of-society, whole-of-government' approaches and multi stakeholder action. If you have the luxury of involving lawyers or policy experts, it is advisable that they analyse the strengths and weaknesses of existing or emerging policies in accordance with evidence-based best practices. This will help to determine what might be negotiable/ not negotiable in the advocacy process.

6 Identify sponsors and policy champions

In all governments – local or national – there are 'champions' who can help sponsor the THR cause. It might be a senator or politician whose family member was saved from an early death by switching from cigarettes to vaping products or who has listened to consumers. Never underestimate the value of strong and articulate sponsors who are willing to champion the cause of a preferred policy. It is important, however, to ensure that relationships with champions are transparent, that they have access to the best science and that regular feedback is provided to the policy champions.

As a THR advocate, also expect attacks from right wing activists. Their discrediting attempts will usually involve claiming that THR advocates are linked to the tobacco industry in one way or the other. Activists rarely risk engaging in real scientific debate about the differentiation of risk between tobacco and nicotine products, and the benefits of THR products to individual and population health. If they do engage, they typically use weak arguments as a blocking tactic, such as claiming that 'more evidence is needed'.

7 Communications Plan

The Bloomberg-funded tobacco control[1] machine has poured millions of dollars into upgrading communications strategies for tobacco control, especially on social media platforms. This communication is certainly helpful for those smokers who are able to quit smoking combustible cigarettes. But for those smokers who cannot or will not quit cigarettes, tobacco harm reduction products such as e-cigarettes, snus and nicotine pouches can provide access to nicotine with much less harm. It is essential to communicate this message effectively on all platforms. Effective advocacy depends heavily on successful communication, which entails:

- Identifying the audiences and developing messages that resonate with them;
- Understanding their needs, concerns, interests, hopes and the best way to attract their attention; and
- If possible, monitor media and social media engagement on your campaign, to measure effectiveness and adapt where necessary.

8 Develop an overarching roadmap/ plan

Most large corporations use a 'plan-on-a-page' system as a visual aid for team members. This system serves as the roadmap for a campaign. It simply states the objectives, summarises strategies and messages, and explains what a successful outcome would look like. This should be a living document; reviewed regularly and adjusted to reflect opportunities, changes and risks in the political ecosystem.

9 Monitoring and Evaluation (M&E)

Monitoring and evaluating is usually the blind spot or flaw in most projects or campaigns. Defining success metrics, reviewing progress and honestly assessing what has not worked will improve the chances of success.

SECTION 2: CONFIDENTLY ENGAGING AND TALKING WITH POLICYMAKERS

This is the key moment in any advocacy campaign. Usually you only have a few minutes to make your pitch to policymakers, so good preparation is vital. Spend time developing your so-called 'elevator pitch for tobacco harm reduction.' Being able to describe your cause concisely and passionately in 30 seconds, could help save many lives! In trying to persuade policymakers to take action on your policy objective, this simple checklist will be useful:

BEFORE MEETING WITH POLICYMAKERS:

- Facts: Understand who you are going to talk to and know about their views on tobacco control and harm reduction;
- Political heat-mapping: Ensure you know what the current views on THR are and the provisions made by current regulations;
- Prepare exactly what you are going to say: Write out your words so it can fit on a T-shirt. Make sure that you have no more than three key, memorable messages. Consider what will be most compelling to an individual policymaker and know what to emphasise (or NOT) to catch their attention;
- Simplify and condense your message: It is essential to create two, maximum three, main points. Most politicians don't have time to read one page, so they usually want half a page, and preferably in two bullet points. All politicians want to retain power, so ensure that your THR argument does not minimise their power; and
- Leave-behinds: Compile a policy brief (max 1-2 pages) that succinctly yet clearly outlines the problem, provides supporting evidence and defines solutions.

DURING THE MEETING:

- Practise the utmost diplomacy and show respect at all times;
- Request for a meeting of 15 minutes, no more than 20 minutes. If you get their attention, they will give you 30 minutes;
- Assistants: As the gatekeepers of the policy makers' time schedules, make a point of cultivating good relationships with the policy makers' assistants and advisers;
- Spokespersons: Policymakers are generally more willing to listen to credible scientists or health professionals – make sure you have the right people in the room that will help, not hinder your cause; and
- At the end of the meeting, confirm the next steps. Policymakers rarely follow up, so once you have clarified any next steps, make sure to follow up. This includes sending a policy brief, any evidence requested and possible dates for future engagement. Adopting quiet diplomacy goes a long way to continue building bilateral communication.

POST-MEETING FOLLOW-UP:

- Always send a thank you note;
- Follow up any next steps in writing. Send an email to summarise the discussion, any consensus points, and the next steps. Make sure to diplomatically articulate all information the policy maker has requested you to provide; and
- Confidentiality: It is vital to ensure that you never disclose any information shared in confidence. Without confidentiality, no relationship is possible. If you are unsure what information can be shared, always err on the side of over-communicating – ask permission to share information. "When in doubt, find out!"

Photo by Adrien Olichon on Unsplash

Photo by Edwin Andrade on Unsplash

SECTION 3: OBJECTION HANDLER: COMMON QUESTIONS & ANSWERS CONCERNING THR, SPECIFICALLY VAPING PRODUCTS

All tobacco control and tobacco harm reduction advocates should expect objections to the principle and science of tobacco harm reduction. There has been extensive debate in the public and social media about these products, so it is wise to understand the concerns and be prepared with thoughtful and evidence-based answers.

In the following section is a selection of common Q&A QUESTIONS about issues relating to vaping products (e-cigarettes) with global premier public health agency, the World Health Organization (WHO) providing their answers/views.[2] Note that the original Q&A section has been adapted to include WHO views on issues relating to main questions found in other online communications.[3]

We have also provided FACTS and answers as they apply to tobacco harm reduction below each question in the WHO Q&A. This will help to ensure the inclusion of accurate and factual information in any THR advocacy campaign. The Q&A section below is reproduced with the kind permission of The Counterfactual.[4]

FREQUENTLY ASKED QUESTIONS

ARE E-CIGARETTES AND OTHER VAPING PRODUCTS DANGEROUS?

WHO: There are many different types of e-cigarettes in use (also known as Electronic Nicotine Delivery Systems (ENDS) with varying amounts of nicotine and harmful emissions.

FACTS: WHO responds to this question with a series of half-truths and non-sequiturs that confuse relative and absolute risk and 'safe' and 'much safer'.

With its statement containing no useful information, it appears the aim is to confuse the reader about the comparison of smoking vaping risks. There is little evidence that the emissions are or are likely to be a cause of serious harm. It is certainly nothing comparable to cigarettes. Though there are differences between ENDS products, these are clustered at the opposite end of the scale of harm caused by smoking.

For all practical purposes, it is the 95-99% reduction compared to cigarettes that matters for policymakers and consumers. Exposure to nicotine itself is not especially harmful and mostly under the control of the user through 'titration' – smoking or vaping in a way that provides the desired nicotine dose.

DO E-CIGARETTES (ENDS) CAUSE LUNG INJURIES?

WHO: ENDS emissions typically contain nicotine and other toxic substances that are harmful to both users and those exposed to the vapours second-hand. Some devices that claim to be nicotine-free have been found to contain nicotine.

FACTS: This answer conveys a basic misunderstanding of nicotine – it is not the nicotine that causes serious harm, it is smoke. As the name suggests Electronic Nicotine Delivery Systems (ENDS) deliver nicotine intentionally and by design.

Nicotine is a legal and relatively mild and innocuous recreational drug with perhaps 1.3 billion users worldwide. The purpose of ENDS is to enable users to use nicotine with a tiny fraction of the risk associated with smoking tobacco. Smoking is by far the riskiest way of consuming nicotine and the cause of most of the tobacco-related non-communicable disease that WHO is supposed to be trying to reduce.

Smoking is especially risky because nicotine is delivered to the lungs in 'smoke' that consists of hot toxic gases and thick, sticky particles resulting from burning or combusting dried and cured tobacco leaf. ENDS do not involve uncontrolled combustion reactions. They also do not create the thousands of newly formed chemicals (many toxic and carcinogenic) that are produced in the burning tip of the cigarette.

ENDS use electrical heat to create a liquid aerosol (a fine mist of liquid droplets) from liquids that contain pure pharmaceutical grade nicotine, neutral excipients and flavourings. This basic difference in technology is why e-cigarettes are so much safer than tobacco cigarettes.

RELATED QUESTION ABOUT WHETHER ENDS CAUSE LUNG INJURIES

WHO: There is growing evidence to show that ENDS use could cause lung damage. On 17 September 2019, the United States Centers for Disease Control and Prevention activated an emergency investigation into links between ENDS use and lung injuries and deaths. By 10 December 2019, the USA reported more than 2 409 hospitalized cases and 52 confirmed deaths. At least five other countries have initiated investigations to identify cases of lung injuries related to ENDS use.

FACTS: This is inaccurate There is not any 'growing evidence that ENDS could cause lung damage of the type seen in the United States between June and December 2019. On the contrary, since July 2019, there has been growing – and now conclusive evidence – that this outbreak had nothing at all to do with ENDS.

Since August 2019 it has been apparent that the severe lung injuries were caused by an additive, Vitamin E Acetate, which is used in cannabis (THC) oils to 'cut' (dilute) the liquid without reducing its viscosity. The use of this additive in THC oils appeared primarily in the illicit US supply chain for fraudulent economic reasons, namely to make more money from expensive THC oil by diluting it.

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LINK BETWEEN VITAMIN E ACETATE AND LUNG INJURIES

In its Q&A question – relating to the claim that vaping causes lung injuries– the WHO omitted the following factual information about Vitamin E acetate in its fact sheet[3]:

- "Vitamin E acetate is the cause of the severe lung injuries seen so far: this substance cannot be added to nicotine e-liquids – it is not soluble in the excipients used in nicotine liquids.
- There is no economic rationale to even try to add Vitamin E acetate or other thickeners. A thickener serves no purpose in nicotine-based e-liquids which do not benefit from being 'cut' [diluted] or thickened.
- No nicotine e-liquids tested following outbreaks of the lung injury have contained suspect ingredients;
- The supply chain for nicotine e-liquids in the United States is legal, regulated and does not substantially overlap with the THC vape supply chain. There is a vanishingly small chance that a completely independent problem with nicotine e-liquids would emerge at the same time, in the same place with the same symptoms as the cases caused by additives to THC vapes. Using the well-established epidemiological techniques used for, for example, isolating causes of food poisoning, it should have been possible to eliminate ENDS as a possible cause in August [2019] at the latest.
- The confusion was caused by, and perhaps promoted by, focussing on the testimonies from lung injury victims claiming to have used only nicotine liquids and not cannabis (THC). However, these accounts are obviously unreliable because of the legal status of THC and the users' risk of committing a crime or facing problems with employment, education or family. There has been no conclusive case where nicotine liquids were established as the cause of the injury.
- CDC now (January 2020) focusses its advice on avoiding THC vapes and Vitamin E acetate, not ENDS - it maintains its customary reserve about ENDS (but no more than that)[5]:

  "CDC and FDA recommend that people not use THC-containing e-cigarette, or vaping, products, particularly from informal sources like friends, family, or in-person or online dealers.Vitamin E acetate should not be added to any e-cigarette, or vaping, products. Additionally, people should not add any other substances not intended by the manufacturer to products, including products purchased through retail establishments.Adults using nicotine-containing e-cigarette, or vaping, products as an alternative to cigarettes should not go back to smoking; they should weigh all available information and consider using FDA-approved cessation medications. They should contact their healthcare professional if they need help quitting tobacco products, including e-cigarettes, as well as if they have concerns about EVALI."

It is notable that the WHO position is not consistent with the CDC's advice, which it cited as its source. The CDC itself has been very slow to recognise that ENDS are not implicated in this outbreak.

For reliable and well-cited information, consult these sources:

- This article in the cannabis specialist publication Leafly, Vape pen lung injury: Here's what you need to know[6]; and
- Also, for those wishing to examine the deceptive elements in the CDC's approach to this outbreak, please consult Dr Michael Siegel's numerous posts from August 2019, The Rest of the Story: Tobacco and Alcohol News Analysis and Commentary.[7]

ARE E-CIGARETTES MORE DANGEROUS THAN REGULAR CIGARETTES?

WHO: There is no doubt that they are harmful to health and are not safe, but it is too early to provide a clear answer on the long-term impact of using them or being exposed to them.

FACTS: The WHO answer starts by missing the point about harm reduction – the products may not be 100% safe, but they are an alternative to using combustible products that may be more than 20 times as risky, based on what we currently know of the toxicity. Furthermore, the statement that "there is no doubt that they are harmful..." is an exaggeration.

Some plausible mechanisms could conceivably cause harm, but it is far from established that ENDS will cause any material harm to the vast majority of users. So far, there is little sign of material harm to users and it is quite possible that when a long-term evaluation is done on ENDS, that the associated harms will be seen as negligible and may even show benefits. What matters most is that if there is any harm at all associated with ENDS, it is certain to be very much less than from smoking. By far the most significant health impact is its benefit in reducing the harm caused by smoking – a fact that the WHO Q&A ignored completely.

RELATED QUESTION ABOUT WHETHER ENDS ARE MORE DANGEROUS THAN REGULAR CIGARETTES

WHO: This depends on a range of factors, including the amount of nicotine and other toxicants in the heated liquids, but we know that ENDS pose clear health risks and are by no means safe.

FACTS: The question itself is unreasonable. No scientist who has researched this believes that the risks associated with ENDS are even close to those of smoking. The wording of the WHO question can easily lead to an 'anchoring bias'. This refers to establishing the idea that the question on everyone's mind is whether ENDS are more dangerous than cigarettes or about the same, thus suggesting parity of risk is the best case for ENDS.[8] This implication is deeply unethical. Moreover, it could have serious health consequences if it causes people to abandon ENDS for cigarettes or not to switch.

The WHO answer provided is a non-answer since the question is whether ENDS exceed 100% of the risk of cigarettes. The WHO's answer is that ENDS do not have zero risk.

There is an active debate about the relative risk of ENDS and cigarettes, but the real question should be "How much less risky are ENDS than cigarettes?" The National Academies of Science Engineering and Mathematics provided more clarity in its 2018 report[9], which stated[10][11] *"While e-cigarettes are not without health risks, they are likely to be far less harmful than combustible tobacco cigarettes."*

In a review of the available science, The Royal College of Physicians concluded in Section 5.5, p.87 of its 2016 report *Nicotine Without Smoke: Tobacco Harm Reduction*[12]:

"Although it is not possible to precisely quantify the long-term health risks associated with e-cigarettes, the available data suggest that they are unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower than this figure."

ADDITIONAL READING: Read more about an irresponsible activist claim that ENDS and cigarettes are equivalent in risk: Vaping risk compared to smoking: challenging a false and dangerous claim by Professor Stanton Glantz.[13]

ARE ENDS ADDICTIVE?

WHO: ENDS are particularly risky when used by adolescents. Nicotine is highly addictive and young people's brains develop up to their mid-twenties. Exposure to nicotine can have long-lasting, damaging effects.

FACTS: These claims about effects on the brain are largely inaccurate and rely on a few experiments done on rodents. There is also no compelling evidence that a history of nicotine use causes recognisable cognitive or other brain-related impairment.

Note that the argument here is not that teen vaping is a good thing, but it is important not to exaggerate the risk only. In addition, it should be placed in context with other teen risk behaviours, such as alcohol use, illicit drugs, reckless driving, underage sex, fighting and bullying etc.

WHO: Yes. Nicotine is highly addictive, and ENDS involve the inhalation of a nicotine-infused aerosol.

FACTS: The WHO answer is a gross over-simplification. First, 'addiction' is a loaded and derogatory term. It is important to carefully define such terminology in professional communication. 'Addiction' usually refers to some type of additional harm (disease, mental impairment, loss of employment, family breakdown) arising from compulsive behaviour. In fact, the WHO itself avoids the term 'addiction' and uses the preferable term: dependence syndrome.[14] According to the WHO definition, a diagnosis of dependence depends on[14]:

Persisting with substance use despite clear evidence of overtly harmful consequences, such as harm to the liver through excessive drinking, depressive mood states consequent to periods of heavy substance use, or drug-related impairment of cognitive functioning; efforts should be made to determine that the user was actually, or could be expected to be, aware of the nature and extent of the harm.

In the case of smoking, the harms are well documented – cancer, cardiovascular disease, respiratory illness etc. But what is the harm arising from vaping? For many, it is the harm reduction that turns nicotine use from a compulsion back into a pleasure they do not wish to forego.

ADDITIONAL READING: The New Nicotine Alliance – Vaping and the Pleasure Principle.[15]

FACTS ABOUT NICOTINE'S DEPENDENCE POTENTIAL

Whether nicotine is dependence-forming is also dictated by how it is delivered, i.e. how quickly it reaches the brain and what peak level it reaches in the blood. Experts refer to this function of the delivery system as the pharmacokinetics or 'PK'. In the case of tobacco smoke, other possible reinforcers may also be involved.

There are no WHO warnings about products such as nicotine replacement therapy. This is because NRT products (patches, gum, etc.) are designed to have no dependence forming characteristics, or to minimise what pharmaceutical regulators call 'abuse liability'. The cigarette is the undisputed champion of nicotine PK (at least for now). This is why smoking is still so popular and why people find it so hard to quit smoking.

Herein lies the catch. Without dependence-forming characteristics, NRTs are not very effective at helping smokers quit smoking. Yet, this is where harm reduction supporters take a different approach. They recognise that as a legal drug, nicotine is unlikely to be banned outright, even though it's widely used in its most dangerous form (cigarette smoking). For this reason, THR supporters focus on the 'reward that vaping provides – to be equal to, or at least competitive with smoking, so it can help users switch from smoking to vaping by choice. Trying to suppress THR products amounts to protecting the cigarette trade from competition. Ironically, so much of the WHO's communication and actions has exactly that effect.

RELATED QUESTION ABOUT ADDICTION AND TEEN USE OF ENDS

WHO: Young people who use ENDS are also more likely to use conventional cigarettes, cigars or hookahs.

FACTS: This statement, while true, is highly misleading since the use of ENDS does not cause cigarette smoking – the so-called 'gateway effect').

It is far more likely that those same influences that incline young people to smoke also incline them to use ENDS. These factors, known as 'common liability' may include genetics, family circumstances, mental health, school environment, delinquency, risk-taking, etc. ENDS are in fact, more likely to be beneficial to young people who use them because they may be diverting them from smoking cigarettes.

WHO: ENDS increase the risk of heart disease and lung disorders. For pregnant women, ENDS pose significant risks as they can damage the growing foetus.

FACTS: This argument is greatly over-stated. There is some evidence of effects on the body from ENDS use – but this is not surprising, given that nicotine is a stimulant. Because nearly every adult ENDS user is a current or former smoker, it is nearly impossible to isolate the effects of ENDS use from the effects of prior smoking. Researchers claiming to 'adjust for smoking history' are unlikely to have the data to do that properly.

ARE SECOND HAND ENDS EMISSIONS DANGEROUS?

WHO: ENDS also expose non-smokers and bystanders to nicotine and other harmful chemicals.

FACTS: The answer indicates a misunderstanding of basic toxicology, that 'the dose makes the poison' and it is the quantity of exposure that matters. Here is how nicotine exposure of vaping actually works:

- Although vaping in public places exposes users to vapour aerosol, the actual nicotine exposure is minimal because most is absorbed in the body of the ENDS user;
- It is not equivalent to the burning tip of a cigarette, which releases sidestream smoke);
- Toxic exposure to non-smokers and bystanders is much lower because vapour aerosol is far less toxic than cigarette smoke; and
- Finally, vapour aerosol dissipates and breaks down much more rapidly than cigarette smoke. As a result, vapour exposure is unlikely to be more than a mild nuisance and issue of social etiquette.

For this reason, property owners and managers should define their own vaping policy, not have it imposed by law.

WHO: Yes. The aerosols in ENDS typically contain toxic substances, including glycol, which is used to make antifreeze. ENDS pose risks to users and non-users.

FACTS: This statement is painfully inaccurate. Glycol is not a chemical itself, but a class of chemicals. The ethylene glycol used in antifreeze is a completely different substance to the propylene glycol used in vaping liquids. This extract from the Encyclopaedia Britannica entry on Glycol[16] provides the facts:

Ethylene glycol (also called 1,2-ethanediol, molecular formula $HOCH_2CH_2OH$) is a colourless, oily liquid possessing a sweet taste and mild odour. It is produced commercially from ethylene oxide, which is obtained from ethylene. Ethylene glycol is widely used as antifreeze in automobile cooling systems and in the manufacture of human-made fibres, low-freezing explosives, and brake fluid. Ethylene glycol and some of its derivatives are mildly toxic.

Propylene glycol, also called 1,2-propanediol, resembles ethylene glycol in its physical properties. Unlike ethylene glycol, however, propylene glycol is not toxic and is used extensively in foods, cosmetics, and oral hygiene products as a solvent, preservative, and moisture-retaining agent. Propylene glycol is manufactured in large amounts from propylene oxide, which is obtained from propylene.

The WHO's incorrect claim of the presence of ethylene glycol in ENDS (which should state the absence) misses the point. Overall, bystanders are exposed to far lower levels of toxins and for much less time in the presence of e-vapour aerosol. Here are three reasons why indoor emissions of vapour aerosol are far less risky than second-hand smoke (also called side stream smoke):

The quantity emitted. The user absorbs most of the inhaled vapour. Only a small fraction is exhaled (15% or less, depending on the constituent). In contrast, the burning tip of a cigarette produces about four times as much environmental tobacco smoke than the smoker exhales. Vaping does not produce any equivalent of this 'side stream smoke'.

The toxicity of the emissions. Tobacco smoke contains hundreds of toxic products of combustion. In vapour aerosol, these are either not present or present at very low levels. Vapour emissions do not have toxins present at levels that pose a material risk to health.

Duration of emissions remaining in the atmosphere. Environmental tobacco smoke persists for far longer in the environment (about 20-40 minutes per exhalation). In contrast, aerosol droplets from e-vapour evaporate in less than a minute and the gas phase disperse in less than two minutes.

Until now, no case exists that this poses a meaningful risk to bystanders, other than being a nuisance. This is not a reason for ENDS use to be allowed everywhere, but it is also not a reason to ban it everywhere by law. The correct balance of responsibilities should rest with allowing property owners or managers to decide where their customers, clients, employees and visitors can use ENDS.

WHO neglects to convey any of this factual and policy-relevant information. Instead the organisation's communications are obscured by generalisations and elementary errors.

RELATED QUESTION ABOUT EXPOSURE TO THE LIQUID IN ENDS

WHO: The liquid in ENDS can burn skin and rapidly cause nicotine poisoning if swallowed or absorbed through the skin. There is a risk of the devices leaking, or of children swallowing the liquid, and ENDS have been known to cause serious injuries through fires and explosions.

FACTS: The source of this misleading information behind the WHO claim is a mystery. There have been no reported cases of skin being 'burnt' by e-liquid or any plausible reason why it would cause burns. Nicotine ingested in large doses can cause poisoning. However, as an emetic, it causes vomiting, severe incidents are thus rare and treatable. As with anything hazardous – medicines, cleaning agents, alcohol – that mitigate risks of accidental exposure, it is advisable to take normal precautions when handling e-liquids. Other precautionary measures include using child-resistant containers and product warning labels, as well as advice on what to do in case of accidents.

There have been a few cases of battery explosions. However, the numbers harmed in this way are a tiny fraction of those injured or killed in smoking-related fires.

ARE SECOND HAND ENDS EMISSIONS DANGEROUS?

WHO: Countries can choose to ban ENDS. ENDS are currently banned in over 30 countries worldwide, with more and more countries considering bans to protect young people.

FACTS: This answers the wrong question and conceals the problems associated with prohibition.A more truthful question would be "Can ENDS be banned?" Yes, it appears that countries have the freedom to ban ENDS. However, if such bans have the aim or effect of protecting the domestic cigarette trade, they may be limited by WTO anti-discrimination law.

ADDITIONAL READING: Policy study: E-vapor product bans could violate international trade rules, R Street Institute.[17]

WHO does not provide an answer to its own question about banning ENDS. Instead, one has to wonder whether the idea is to normalise the idea of bans and to create a default effect as it provides no valid grounds to justify banning ENDS. To provide an accurate answer would mean having to discuss the likely unintended consequences of such a ban. These include:

- Current vapers reverting to smoking;
- Current smokers not switching to vaping;
- New adolescent users taking up smoking instead of vaping;
- Boosting the cigarette trade;
- Encouraging the development of widespread home DIY mixing;
- Resulting in the development of a black market in vaping products – with issues of quality and consumer rights and loss of regulatory supervision;
- Enriching criminals and increasing crime in illegal products;
- Exposing more people to criminal suppliers who also supply illicit drugs and other illegal commodities; and (above all)
- Infringing on the basic right to the liberty and autonomy for people to control their own risks, make their own decisions and take their own initiatives to protect their own health at their own expense.

SHOULD ENDS BE REGULATED?

WHO: Yes. ENDS are harmful to health and, where they are not banned, they must be regulated. WHO recommends that countries implement regulatory measures that best fit their domestic context. Regulation should:

- *Disrupt the promotion and uptake of ENDS products;*
- *Reduce the potential health risks to ENDS users and non-users;*
- *Prohibit false or unproven claims from being made about ENDS; and*
- *Protect existing tobacco-control efforts.*

About 15 000 unique flavours are used in ENDS, including flavours designed to attract young people, like bubble gum and cotton candy. Governments should restrict ENDS advertising, promotion and sponsorship so young people, other vulnerable groups and non-smokers are not targeted.

The use of ENDS in indoor public and workplaces should be banned, given the health risks posed to non-users. Taxing ENDS in a similar way to tobacco products offers a win-win for governments by protecting citizens through higher prices that deter consumption.

FACTS: The WHO answer entirely ignores the potentially harmful and unintended consequences of the proposed policies. There are very few pro-harm reduction advocates that argue for zero regulation, and much consumer protection regulation applies by default in every jurisdiction. The question is what is the right form of regulation? To understand this, policymakers need to consider not only what they are trying to achieve with regulation, but also what unintended harmful consequences such regulation may have (see the example of a prohibition at Q6 above). For example, a ban on advertising ENDS has the effect of protecting the current market (cigarettes) from the disruptive entrant (ENDS). A ban on flavours, especially if it is wide ranging, can make ENDS less appealing to adult smokers and mean that fewer people switch.

ADDITIONAL READING: Risks of excessive regulation: Plausible unintended consequences of excessive regulation of low-risk nicotine products.[18]

The Royal College of Physicians summarised this well in Section 12.10, p.187 of its report[12]:

However, if [a risk-averse, precautionary approach to e-cigarette regulation] also makes e-cigarettes less easily accessible, less palatable or acceptable, more expensive, less consumer friendly or pharmacologically less effective, or inhibits innovation and development of new and improved products, then it causes harm by perpetuating smoking. Getting this balance right is difficult.

It is indeed challenging to strike this balance. However, in doing so, policymakers should once again be mindful that smoking is vastly riskier than ENDS use and therefore unintended effects that cause harm by perpetuating smoking' should be uppermost in the appraisal of policy. In addition, it should be strongly weighted against the possibility of creating more smoking. WHO is failing in its task to protect people by minimising or ignoring the risks of harms caused by regulation and dismissing the unintended consequences of badly designed or excessive policy interventions.

So, what is the right approach to regulation? Regulation of tobacco and nicotine products should be 'risk-proportionate 'with more stringent controls placed on the highest risk products. In practice, this means:

- Introducing high taxes on cigarettes, but low or no taxes on e-cigarettes;
- Putting bans on cigarette advertising, but implementing controls on content and placement of e-cigarette advertising to prevent marketing to teens;
- Banning smoking in public places, but leaving the decisions about vaping policy to the owners or managers of buildings;
- Including large graphic health warnings on cigarettes, but inserting messages encouraging switching to e-cigarettes either on or inside the packaging of both cigarettes and e-cigarettes;
- Using plain packaging for cigarettes but not for e-cigarettes;
- Regulating product formulation that makes switching to vaping relatively more attractive than continuing to smoke;
- Implementing regulation that addresses electrical, chemical, thermal and mechanical product risks, where these benefit consumers;
- Regulating the design of containers to make them child-resistant;
- Implementing differential age restrictions, for example, age 21 for cigarettes, but age 18 for e-cigarettes;
- Banning Internet sales of cigarettes, but not of e-cigarettes;
- Having stop-smoking centres that are vaping friendly services;
- Implementing campaigns that discourage smoking, but encourage switching.

ADDITIONAL READING

- Anti-vaping arguments: Ten perverse intellectual contortions: a guide to the sophistry of anti-vaping activists[19]; and
- Risk-proportionate regulation of tobacco and nicotine products: Read more here in a proposal made in August 2019 relating to New Zealand[20].

DO ENDS HELP YOU QUIT SMOKING?

WHO: There is not enough evidence to support the use of these products for smoking cessation. For tobacco users looking to quit, there are other proven, safer and licensed products, such as nicotine replacement therapies (such as patches and gums), as well as quit lines, mobile messaging and specialized tobacco dependence treatments.

FACTS: In this answer, WHO uses a sweeping generalisation, ignoring or dismissing the actual evidence. The only way WHO could support a claim like this is if it ignores the extensive available evidence or sets an impossibly high standard for certainty that it does not apply to its preferred methods or to anything else.

There are currently four strands of evidence that suggest e-cigarettes are effective in helping people to quit smoking:

- Evidence from randomised controlled trials, notably, Hajek et al.[21], which showed vaping to be about twice as effective as NRT; "E-cigarettes were more effective for smoking cessation than nicotine-replacement therapy, when both products were accompanied by behavioural support."
- Observational studies (watching what happens when people use e-cigarettes) for example, Jackson et al.[22], "Use of e-cigarettes and varenicline are associated with higher abstinence rates following a quit attempt in England."
- Population data (unusually rapid reductions in smoking prevalence and cigarette sales), for example, Zhu S-H et al.[23], "The substantial

increase in e-cigarette use among US adult smokers was associated with a statistically significant increase in the smoking cessation rate at the population level. These findings need to be weighed carefully in regulatory policy making regarding e-cigarettes and in planning tobacco control interventions."

- Thousands of testimonials by users who have struggled to quit using other methods. See, for example, CASAA testimonials.[24]

ADDITIONAL READING: Before dismissing 'anecdotes', make sure to read Carl V Phillips on why Anecdotes ARE scientific data.[25]

None of these evidence strands are decisive in themselves. However, all four sources indicate that e-cigarettes are displacing smoking. If one adds common sense, surely an alternative way of taking nicotine – with a fraction of the health risk and stigma and combined with other attractive features – should be expected to displace smoking as technology evolves. It would require strong evidence for the notion that ENDS somehow increases smoking or leaves it unchanged. No such evidence currently exists.

WHAT IS WHO DOING ABOUT ENDS?

WHO: WHO regularly monitors and reviews the evidence on ENDS and health and offers guidance to governments and the public. This includes the biennial WHO Report on the Global Tobacco Epidemic, which tracks the status of the tobacco epidemic and interventions to combat it and other relevant resources. WHO strives to build a safer, healthier world for everyone, everywhere.

FACTS: Despite its response in the WHO Q&A, there is no sign that WHO monitors or reviews the evidence in any comprehensive or attentive way. Regrettably, the organisation uses information selectively, distorting and fabricating evidence, which it uses to mislead the public and government to pursue its prohibitionist 'abstinence-only' agenda.

WHO mentions the report, WHO Report on the Global Tobacco Epidemic[26], a publication that is highly hostile to ENDS. The following passage from the report typifies its use of emotive language in describing ENDS[26]:

These products are aggressively marketed or promoted as cleaner alternatives to conventional cigarettes, as smoking cessation aids, or as "reduced risk" products. They have proliferated in several markets around the globe and present a unique challenge to regulators. While some of these products have lower emissions than conventional cigarettes, they are not risk free, and the long-term impact on health and mortality is as-yet unknown.

WHO ignores a giant conflict of interest embedded in its operations. Even more disturbing is that WHO's work in this field is also built on a conflict of interest that should be a source of real concern to those involved in WHO governance. The above-mentioned report[26] was made possible by a grant from Bloomberg Philanthropies. Furthermore, it features a foreword by Michael Bloomberg and Bloomberg-funded staff had input.

Figure 1: WHO takes the Bloomberg dollar for its anti-vaping report (found on p.108 of the report)[26]

In his foreword, Bloomberg highlights his role as the WHO Global Ambassador for Noncommunicable Diseases and Injuries Founder, Bloomberg Philanthropies, and brags about his influence over the organisation(found on p.17 of the report)[26]:

The World Health Organization and Bloomberg Philanthropies are committed to accelerating the reduction of tobacco use worldwide. The challenges are daunting, but together, we are proving that this is a winnable fight.

Bloomberg Philanthropies works in close partnership with Director-General Tedros Ghebreyesus and WHO to combat NCDs and global support for effective policies is growing. Though it claims that the WHO did all the work the report acknowledges substantial Bloomberg-funded staff contributions.


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A section from WHO report on the global tobacco epidemic, 2019: Offer help to quit tobacco abuse, p.105[26]

The involvement of the Bloomberg (and Gates) foundations in the tobacco control programmes of the WHO and the World Bank is described in more worrying academic detail by Mukaigawara et al. in Balancing Science and Political Economy: Tobacco Control and Global Health.[27] This article includes the following figure, which shows how Bloomberg also funds NGOs that interact with WHO – many of which have observer status at the FCTC meetings.

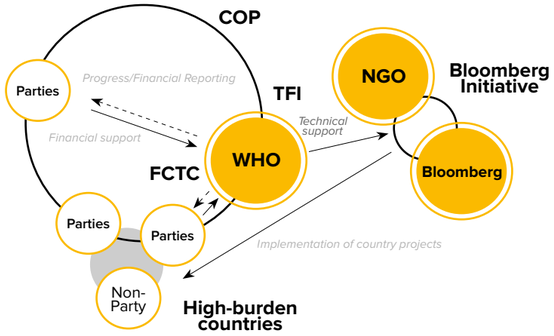

Figure 4. Governance structure of the World Health Organization's (WHO) tobacco control programme. The WHO functions as the secretariat of the FCTC and the TFI. The FCTC is funded by the voluntary assessed contributions and extra-budgetary funding, the former from the Parties of the FCTC. The WHO is accountable to the Parties, and documents are available on its public website. The TFI produces technical reports, but its country projects are implemented as the Bloomberg Initiative to Reduce Tobacco Use. The WHO is a part of this initiative, but has no authority in the selection of funded projects. Abbreviations: Bloomberg = Bloomberg Philanthropies; COP = Conference of Parties; FCTC = Framework Convention on Tobacco Control; NGO = Non-governmental organisations; TFI = Tobacco Free Initiative. Sources: http://www.who.int/fctc/en/, http://www.who.int/tobacco/about/partners/bloomberg/en/

Figure 3: Governance structure of the WHO tobacco control programme[27]

Why should we care about Bloomberg money propping up WHO? In a January 2020 interview with the New York Times, Mr Bloomberg declared himself in favour of prohibiting vaping products.[28]

Interviewer: Would you ban vaping products entirely? Bloomberg (answering as a US presidential candidate): I think you can make a very good case to do so. It would be great if the President did that.

In other words, he takes the most hostile possible position against ENDS – as an outlier. Bloomberg is a financial services billionaire with no special expertise on public health and no experiences of the lives directly affected by these policies. Undaunted by his inexperience, he nevertheless holds very strong views on ENDS and other tobacco-related issues.

He is entitled to his poorly-informed opinions, but the WHO shareholders (i.e. governments) should be wary that the Bloomberg empire is not a neutral funder as it has displayed strong policy preferences. For example, Bloomberg has provided $160m to ban flavoured e-cigarettes: Bloomberg to spend $160 million to ban flavoured e-cigarettes.[29] However, it is very likely that such a prohibitionist move would cause far more harm than good.

ADDITIONAL READING: The US vaping flavour ban: Twenty things you should know.[30]

PREFERRED FUTURE ROLE FOR THE WHO?

Here are some considerations, how WHO might become more impactful in THR:

- The anti-vaping Q & A page[2] should be taken down and the content withdrawn. In addition, it should no longer be endorsed as a WHO view. This error-filled information should really be seen as a symptom, a manifestation of deeper causes, rather than the underlying problem. The fact that the page has since been updated does not change the underlying conditions that allowed the original version to be published. The remaining recommendations address the underlying cause.
- It is important to stop the anti-ENDS and anti-harm-reduction activism that lacks evidence within the WHO. Instead, heed the wiser (albeit quieter), voices in the expert community and pay attention to the many consumers with real-life insights and direct experience. Then rethink the organization's approach to innovation and tobacco harm reduction. For example, study this letter, to WHO Director-General Dr Tedros Adhanom Ghebreyesus, compiled in October 2018 by 72 experts in nicotine policy and science, Innovation in tobacco control: developing the FCTC to embrace tobacco harm reduction.[31] Another good read is the article by Professor Robert Beaglehole and others published in The Lancet, in August 2019. Nicotine without smoke: fighting the tobacco epidemic with harm reduction.[32] In it, the authors argue for a more constructive approach by WHO.
- Improve scientific credibility in THR by reconstituting its advisory committee (TobReg).[33] Rely more heavily on expert advice for evidence-based policy-making rather than using hand-picked consultants to provide policy-based evidence-making service to bolster the organisation's otherwise unsupportable positions. This is also important to avoid public trust haemorrhaging from one part of the organisation to the detriment of the credibility of the entire WHO.
- Raise the quality of science capabilities in the Tobacco Free Initiative and FCTC Secretariat by appointment, training or secondment. In addition, improve the quality and importance of scientific challenge within the WHO's tobacco control functions.
- It is pointless to criticize the person(s) that wrote the misleading Q & A, as this involves the issue of governance and quality control. It is more important to determine who signed off the Q&A and who takes responsibility for the scientific integrity of WHO's public communications. If the accountability is unclear, then the WHO's Executive Board should investigate the matter further and resolve it.
- Stop accepting funding from external organisations that create obvious conflicts of interest because of their own very obvious advocacy and policy agendas. In the case of ENDS and tobacco harm reduction, the excessively intimate involvement of Bloomberg-funded activist entities like Bloomberg Philanthropies, Campaign for Tobacco-Free Kids and Vital Strategies is corrosive to the WHO's independence and objectivity and should cease.
- Refine the WHO's guidance on Engagement with non-state actors[34] to protect tobacco and nicotine policy from interference from ideological and other vested interests of wealthy activists.

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