



Assessing the Efficacy of THR Interventions

in Brazil, China, Egypt, Indonesia, South Africa, and Turkey

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CAMBRIDGE DESIGN PARTNERSHIP
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CONTENTS

Image: whitepaper report cover “Five approaches to improve smoking cessation outcomes and reduce tobacco harms globally”



“Designing and implementing strategies for eliminating or reducing the consumption of tobacco products presents a significant challenge due to regional discrepancies in availability, awareness, efficacy, and legal status of THR interventions. In this white paper, we seek to navigate the complexity of THR to evaluate which interventions, and combinations of interventions, are proving most efficacious. We also look at emerging trends, such as the potential rise in adoption of novel products including heated tobacco, snus, and oral NPs as smoking cessation aids.”

Ben Illidge

Head of Tobacco Harm Reduction,
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Overview

Tobacco smoking is a public health risk causing around eight million deaths annually. Over 80% of the estimated tobacco users worldwide (approximately 1.3 billion) are in low- and middle-income countries. Tobacco harm reduction (THR) strategies can be characterized as decreasing tobacco-related health risks or switching to a less harmful nicotine-containing product.

In response to the global impact of tobacco smoking, the World Health Organization (WHO) has published the Framework Convention on Tobacco Control (FCTC), including strategies for eliminating or reducing the consumption of tobacco products to accelerate the reduction of tobacco harm.

This white paper reports on a systematic review and quantitative assessment of the availability, awareness, efficacy and legal status of THR interventions in six countries - Brazil, China, Egypt, Indonesia, South Africa, and Turkey - each representing a separate WHO region.

A proposed framework for the ranking of tobacco interventions is applied to each country, allowing for contrast and comparison of tobacco control interventions on a country-by-country basis. Significant differences across countries have been identified, highlighting the difference in tobacco control approach globally. Therefore, greater effort is required to reduce the discrepancies in tobacco control measures and increase the type and availability of effective interventions.

The most suitable interventions identified were Nicotine Replacement Therapy (NRT), varenicline, counseling, e-cigarettes/Electronic Nicotine Delivery Systems (ENDS), quitlines, and text message support.

Overall, the interventions achieved the highest scores in Brazil, and the lowest scores in Turkey.

Although limitations in data availability make it difficult to make relative comparisons, it is evident that the use of pharmacotherapy for smoking reduction or abstinence continues to be one of the most effective tools for tobacco control.

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Introduction





Tobacco smoking is a public health risk causing around eight million deaths annually worldwide (1). Of these, approximately seven million are directly related to tobacco use, whereas 1.3 million are linked to second-hand exposure among non-smokers. Of the estimated 1.3 billion tobacco users worldwide, over 80% reside in low- and middle-income countries (1).

The diversity of the term 'THR' implies a lack of consensus on reducing harm through lower-risk alternatives. Definitions range from an approach to decreasing the health risks related to tobacco smoking that may or may not involve complete nicotine abstinence (2), to switching to a reduced-risk nicotine-containing product for those not able to quit smoking (3).

A framework for tobacco control

In developing the FCTC – a treaty providing legal provisions for international health cooperation and establishing standards for compliance (1) – WHO has set out strategies for eliminating or reducing the consumption of tobacco products and exposure to tobacco smoke (4).

The treaty came into effect in 2005 (1) and was ratified by 182 parties in August 2023 (5), with each respective country legally bound to treat tobacco use and dependence in accordance with the guidelines (6).

WHO also introduced a method known as MPOWER in 2007 (1), with the aim of facilitating the implementation of the FCTC interventions at a country level (7). Measures include monitoring tobacco use and prevention policies, protecting people from tobacco use, offering help to stop tobacco use, warning about the dangers of tobacco use, enforcing bans on tobacco advertising, sponsorship and promotion, and raising taxes on the sale of tobacco products (1).

WHO groups its member states into six regions (8): Africa, Americas, Europe, Eastern Mediterranean, Western Pacific, and South-East Asia (8, 9), with South Africa, Brazil, Turkey, Egypt, China, and Indonesia representing a different WHO region respectively (9). WHO Tobacco control advisors are present in each regional office (10). All the countries have ratified the WHO FCTC (5), except for Indonesia, though the country has implemented tobacco control measures (11, 12).

Approaches to smoking cessation

There are several smoking cessation approaches and/or harm reduction strategies, which were identified in a previous scoping review of literature from studies conducted worldwide. The results from this review identified globally available strategies to potentially reduce tobacco use or provide reduced-risk products to the public. These include psychological interventions, NRT, non-nicotine medicines, herbal remedies, and the use of other nicotine-containing products (often regulated as tobacco products), either alone or in combination.

Media formats identified included audiobooks, leaflets, digital storytelling, educational games and booklets, mobile phone applications, motivational text messaging, social media and video-based interventions, virtual cessation coaches, virtual reality, and web-based programs. The literature showed that medicines containing bupropion (e.g. Zyban®), clonidine, cytisine (e.g. Tabex®), varenicline (e.g. Champix®), naltrexone, Vernonia cinerea, and different NRTs in the form of gum, inhalers, patches, lozenges, and nasal sprays, have been used for smoking cessation.

Additional interventions included e-cigarettes or ENDS, heated tobacco, snus, and oral Nicotine Pouches (NPs).

Service-based approaches included advice from healthcare professionals, non-cognitive and Cognitive Behavioral Therapy (CBT), counseling, hypnotherapy, mindfulness, motivational interventions including the 5As model (Ask, Advise, Assess, Assist, and Arrange) and 5Rs model (Relevance, Risks, Rewards, Roadblocks, and Repetition), smoking cessation programs in community pharmacies, and telephone lines to support smoking cessation (e.g. quitlines).

Other interventions included acupuncture, exercise, financial incentives, transcranial magnetic stimulation treatment, and using one's own willpower to quit smoking.

Considerations for application

Due to the ambiguity of the regulatory landscape potentially hampering availability of interventions in different countries, where some may be deemed illegal/unlawful, it was necessary to consider the availability, awareness, efficacy, and legal status of each of the identified interventions in Brazil, China (including Hong Kong), Egypt, Indonesia, South Africa, and Turkey.

This report does not seek to classify harm reduction, nor suggest that the smoking cessation methods mentioned are by any means classified as harm reduction tools. The data presented reflects information found on methods used by vastly differing markets and how these different markets are implementing smoking cessation methods to curb the incidence of tobacco use in that specific population.

Main findings



Historically, there have been different interpretations of the definition of harm reduction in the context of smoking cessation despite countries having agreed to the FCTC, implying the need to implement more uniform strategies to decrease or eradicate the consumption of tobacco products and tobacco smoke exposure.



























A previous scoping review identified diverse smoking cessation and harm reduction strategies, and included searches to ascertain the availability, awareness, efficacy, and legal status of those strategies in each of the six countries. A framework was developed and applied to assess the outcomes of each country's intervention.

As Table 1 shows, the scores for identified smoking cessation/harm reduction interventions vary per country, with China scoring highest in the framework, followed by Brazil, Egypt, Indonesia, South Africa, and Egypt, with Turkey scoring the lowest.



Image: Anti-smoking poster in Indonesia, photo taken during initial CDP research

Table 1 – Summary of the score for each identified smoking cessation/harm reduction intervention per country.

CATEGORY	INTERVENTION	BRAZIL	CHINA	EGYPT	INDONESIA	SOUTH AFRICA	TURKEY	CATEGORY	INTERVENTION	BRAZIL	CHINA	EGYPT	INDONESIA	SOUTH AFRICA	TURKEY
MEDIA	 Audiobooks	0	0	0	0	0	0	RECREATIONAL NICOTINE PRODUCTS	 E-cigarette device/ENDS	8	18.4	13.3	14.7	5	8
	Digital storytelling	0	0	0	0	0	0		 Heated tobacco	1	5	5	18	5	3
	Motivational text messaging	10	18.8	5	12	9.7	14		 Snus	5	5	5	5	5	1
	Social media-based interventions	0	0	21	9	9	3		 Nicotine pouches	5	0	5	18	5	0
	Video-based interventions	0	15	0	0	0	0	PSYCHOLOGICAL INTERVENTIONS	 Professional healthcare advice	5	5	16	15.1	14	5
	Virtual coach/online mentor	9	0	0	0	0	0		 Individual or group counseling	13.6	13.2	18	14.9	15.5	13.1
	Digital educational games	0	0	0	0	0	0		 Cognitive behavioral therapy	13	0	14.5	5	14	16
	Mobile phone apps	0	17.4	0	7	0	0		 Hypnotherapy	12	0	0	5	0	0
	Web-based programmes	7	12	0	0	12	6		 Mindfulness	12.7	0	0	0	0	0
	Books	12	0	0	5	0	0		 5 As model	5	16	5	8	14	14.6
Educational booklets/leaflets	12	14	16.5	5	12	8	 5 Rs model	0	0	0	0	0	0		
MEDICATION OR HERBAL REMEDY	 Champix®/Varenicline	14.3	18	16.5	6.3	20	16	 Community pharmacy	8	5	0	9	0	5	
	 Bupropion	13.5	5	16	1	5	16	 Quitline/ helpline	12	20	12	10	14	10	
	 Tabex®/Cytisine	0	0	0	0	5	0	OTHER SOLUTIONS	 Acupuncture	12	13.5	0	0	0	0
NICOTINE REPLACEMENT THERAPY [NRT]	 Nicotine inhaler								 Exercise	5	5	5	5	5	5
	 Nicotine patches								 Financial incentive	0	0	0	0	0	0
	 Nicotine tablets	8.3	12.2	3.75	15	9.8	13		 Own willpower	10.2	5	14.5	14	19	5
	 Nicotine nasal spray														
	 Nicotine gum														
							COUNTRY OVERALL SCORE	213.6	223.5	192.05	202	198	161.7		

China results do not include Hong Kong results.





Suitable cessation strategies

The framework results indicated that the most suitable smoking cessation/harm reduction strategies relate to NRT, varenicline, counseling, behavioral therapy, the 5As model, healthcare advice, e-cigarettes/ENDS, quitlines, booklets/leaflets, text message support, and the individual's own willpower.

Smoking cessation services that were accessed through the country's national health care system were publicly available and usually free, and these services normally comprised behavioral counseling or advice. Following the 5As model or a similar approach has been recommended in some countries, such as Brazil, China, and Egypt. In some instances, telephone counseling sessions were also available to the public.

In terms of smoking cessation medications, varenicline and bupropion are drugs used for smoking cessation and usually require a prescription to access them. NRT products are available in all these countries, with some requiring a prescription.

Aiding interventions with pharmacotherapy

“There is an emotional need for support from a human perspective whenever a person attempts...quitting smoking. Add to this the benefit of NRT treatment to lower the withdrawal symptoms...and the chances are greater that the smoker will be successful in their attempt.”

Smoking cessation pharmacotherapy has proven to be effective, and no differences in smoking abstinence rates have been found between free and paid treatments. Nonetheless, combining NRT with counseling or behavioral techniques appears to be more effective than pharmacotherapy alone. In Brazil and South Africa, combining NRT with counseling or CBT helped to drive cessation levels. It can be assumed that the support that smokers receive when they want to stop smoking is an interpersonal aspect that plays a major role in people's behavior.

There is an emotional need for support from a human perspective whenever a person attempts something new, such as quitting smoking. Add to this the benefit of NRT treatment to lower the withdrawal symptoms (physical discomfort) experienced when the smoker attempts to stop smoking; and the chances are greater that the smoker will be successful in their attempt.

NRT is more affordable and readily accessible in most markets. However, other pharmacotherapy products have also proven more effective when combined with CBT. Therefore, complementing any pharmacotherapy with additional support appealing to emotional need, such as counseling, quitlines, text message, or mobile apps, is likely to positively impact abstinence rates.

Maximizing the message through media

Booklets or leaflets – which are typically legal and widely available – appeared to be a suitable intervention per the framework score. Although they did not prove more effective than other interventions, such as videos or text messaging, in markets such as China and Turkey their value as a smoking cessation aid is still evident.

Amplifying advice through training

In the literature, we found that the lack of preparation and confidence of many healthcare professionals in providing smoking cessation advice, or even encouraging it, is leading to these services not being offered. In addition, healthcare professionals are one of the main points of contact for individuals wishing to quit smoking, including those unaware of the resources.

Considering this, and that healthcare advice is deemed a suitable intervention per the framework results, adequate training of healthcare professionals to provide smoking cessation advice is key in terms of awareness and support during treatment.

Making the most of medicines

With regard to medicines for smoking cessation, diverse NRT products are legal in all the countries assessed, whereas varenicline and bupropion are legal in all countries except for Indonesia. A reasonable explanation for this discrepancy could be that all the countries have ratified the FCTC except for Indonesia. The WHO announced the inclusion of varenicline and bupropion on the essential medicines list in 2021 (158), stating they have proven to be safe and effective, and their inclusion was a signal to citizens, doctors, public health professionals, and authorities of their availability as an intervention (158).

The WHO Model List of Essential Medicines (23rd list, 2023) includes the following as medicines for nicotine use disorders: bupropion (tablets, 150 mg hydrochloride); NRT (2 mg and 4 mg polacrilex chewing gums, 2 mg and 4 mg lozenges, 1 mg per actuation oral spray, and 5-30 mg/16 hours and 7-21 mg/24 hours transdermal patches); and varenicline (0.5 mg and 1 mg tablet) (159).

Therefore, it is plausible that varenicline and bupropion were deemed illegal in Indonesia as they had not ratified the FCTC approach at this time. However, as the data on the legal status of varenicline and bupropion in Indonesia came from the 2021 WHO report on Indonesia's MPOWER measures (due to a lack of access to the Indonesia medicines database), it is not clear whether changes in the legal status of varenicline and bupropion occurred between the publication of the WHO report and the time of writing.

Meanwhile, the legal status of cytisine deserves a mention, as South Africa was the only country to list medications containing cytisine in its national medicines database. A 2021 WHO expert committee's publication on the selection and use of essential medicines recommended adding cytisine to the WHO essential medicines list and accessing them as an over-the-counter choice (160). The publication also suggested that including cytisine together with bupropion and varenicline will make tobacco cessation medications more accessible, especially in middle and low-income countries, and possibly for indigenous people (160).

That said, the 23rd WHO list released in 2023 has not added cytisine among its essential medicines for nicotine use disorders (159), so it is plausible to hypothesize that if it is included, further changes in cytisine's legal status and availability will be expected for those countries implementing the WHO framework approach.



The introduction of new THR products

Notwithstanding the above, the tobacco products market has evolved with the introduction of new products, such as e-cigarettes, heated tobacco products, snus, and oral NPs. The regulatory landscape is different for each country and constantly evolving.

E-cigarettes

E-cigarettes are legal in Egypt, Indonesia, and China. In South Africa, e-cigarettes are legal if marketed as pharmaceutical products. Conversely, Hong Kong and Brazil have banned the sale of e-cigarettes.

In this respect, available data in Brazil identified that e-cigarettes could be marketed if they receive authorization from Agência Nacional de Vigilância Sanitária (ANVISA). Similarly, while Turkey has prohibited e-cigarette import, it is reasonable to conclude that e-cigarettes can be marketed if domestically produced and receive a marketing authorization. Overall, the regulatory differences on e-cigarettes across countries hamper drawing conclusions of the common reasons leading to their ban or classification as pharmaceuticals or consumer products.

Possible explanations behind the classification of e-cigarettes as pharmaceuticals could be that these products usually contain synthetic or tobacco-derived nicotine, and so, per the national legislation on nicotine and tobacco products, e-cigarettes may fall under the tobacco products or the pharmaceuticals legislation.

In spite of this, recent changes observed in China and South Africa may provide insights into potential regulatory changes in other markets. In China, all flavors in e-cigarettes, except for tobacco flavors, have been banned since 2022. Meanwhile in South Africa, a new bill is under consideration in which e-cigarettes could be accessed without need to be dispensed by pharmacies.



It is plausible that access to e-cigarette products in countries with no strict regulations may become easier, with potential restrictions surrounding flavors that may be appealing to youth. For example, the United States Food and Drug Administration denied a marketing order for two menthol e-cigarettes, noting that the data did not sustain an added benefit from the submitted products for adult smokers compared to tobacco-flavored e-cigarettes (161). It also noted that data from the 2022 National Youth Tobacco Survey indicated that non-tobacco-flavored e-cigarettes presented a known and substantial risk regarding youth appeal, use, and uptake, as opposed to tobacco-flavored e-cigarettes, which did not show the same degree of risk (161).

According to the framework applied, e-cigarettes may be a suitable tool for smoking cessation, with smokers commonly reporting this as a reason for initiating their use. However, studies with a follow-up of ten years or more are required to corroborate sustained smoking abstinence with e-cigarette use, whether such e-cigarette use is temporary or permanent, and the long-term effects of e-cigarette use on the individual's health.

Heated tobacco products, snus, and oral NPs

Heated tobacco products, snus, and oral NPs for smoking cessation did not seem to be a popular option for smoking harm reduction, and limited data was available on these products. The same regulatory status for e-cigarettes applies to heated tobacco products in Brazil, Egypt, Hong Kong, Indonesia, South Africa, and Turkey, whereas in China, heated tobacco products are regulated as cigarettes.

Regarding snus, there are differences in both terminology and status across regulations. In many cases, snus is not specifically cited in the legislation, and terminology covers a broad range of oral smokeless tobacco products, rather than specific types of smokeless tobacco products.

In this respect, snus is considered legal in China, Egypt, Indonesia, and South Africa, based on the interpretation of the available legislation, while oral smokeless tobacco products are banned in Hong Kong and Turkey. No register of snus and oral NPs has been found in the ANVISA database for Brazil, but they can be legally marketed if obtaining corresponding marketing authorization. No restrictions have been found in the present systematic review for oral NPs in China, Egypt, and Turkey. We can postulate that oral NPs fall under the category of other

tobacco processing products in Indonesia, as well as under the classification as pharmaceuticals in Hong Kong and South Africa, based on the interpretation of their national legislation.

In general, the legislation significantly varies from country to country in relation to heated tobacco, snus, and oral NPs. From the available evidence, the tobacco products and nicotine classification in national laws, as well as the definition of new tobacco products in the corresponding laws, are crucial for ascertaining the legal status of these interventions, and in turn, forecasting potential market trends related to heated tobacco, snus, and oral NPs.

Due to the novelty of these products, regulation has struggled to keep up and countries are reacting by adapting legislation to regulate or ban them. The regulatory disparities observed between countries constitute a barrier to quitters where such regulations hamper the availability of these interventions in licit markets.

As the current regulation develops in coming years to adapt to consumers' needs and demands, we foresee an increase in the adoption of these products as less harmful alternatives to smoking or as smoking cessation aids.

The discussion of the identified smoking cessation methods for each market does not seek to define harm reduction or promote these methods over any others. Furthermore, the smoking cessation methods used in the various markets were not evaluated for safety or age-related appropriateness, which differ from market to market. These various methods need to be evaluated independently for the risks or benefits they could provide when they are considered for use as a smoking cessation method.

“As the current regulation develops in coming years to adapt to consumers' needs and demands, we foresee an increase in the adoption of [heated tobacco, snus, and oral NPs] as less harmful alternatives to smoking or as smoking cessation aids.”



Application of framework



Through application of a novel framework assessing tobacco control interventions for availability, awareness, efficacy and legal status, we have made a comparison of different interventions in Brazil, China, Turkey, Egypt, Indonesia and South Africa.

Lack of available data related to some interventions and within some countries has limited the application of the framework for comparison. However, despite these limitations, it has been possible to evaluate and compare interventions on a country-by-country basis.

Of the six countries assessed, China scored the highest on the application of interventions followed by Brazil, Egypt, Indonesia, South Africa, and Egypt, with Turkey scoring lowest. Differences exist in the availability, access and efficacy between countries where complete data were available on the following interventions: e-cigarettes/ENDS, heated tobacco products, varenicline, bupropion, NRT, text messaging support, booklets/leaflets, and quitlines.

The contrast in scoring from intervention to intervention and country to country provides a qualitative indication of their availability, awareness and accessibility in each country.

The legal status of e-cigarettes/ENDS in half of the countries assessed limits their potential to reduce the risk of tobacco.



Images: No smoking signs, photos taken during initial CDP research



Conclusion





Reducing the risk from tobacco is the focus of tobacco control measures through both smoking cessation and THR interventions. The accessibility of the greatest number of effective interventions to aid tobacco abstinence or reduce the harm caused by tobacco plays a crucial role in tobacco control measures.

In this research, a proposed framework for the ranking of tobacco interventions is applied to several countries (Brazil, China, Egypt, Indonesia, South Africa and Turkey), allowing for a contrast and comparison of tobacco control interventions on a country-by-country basis. Significant differences across countries have been identified, highlighting the difference in tobacco control approach globally.

Despite limitations in available data providing barriers to relative comparisons, there is a vast contrast in the awareness, accessibility and efficacy of various interventions across Brazil, China, Egypt, Indonesia, South Africa and Turkey.

Combining interventions for enhanced efficacy

The use of pharmacotherapy for smoking reduction or abstinence continues to be one of the most effective tools of which smokers are usually aware. Pharmacotherapy combined with other supporting interventions such as counseling, text messages, mobile applications, behavioral therapy, healthcare advice, own willpower, or quitlines is likely to increase success rates, as the human factor cannot be ruled out during smoking cessation treatment.

To this effect, improvements are required in the training of healthcare professionals. In addition, consideration should be given to the cost of the medicines, as a high cost may constitute a barrier to use as a smoking cessation tool, in particular for smokers with a low income or difficult financial situations.

On the other hand, the use of other tobacco or nicotine products for smoking cessation/harm reduction may be an option, but it has not been proven to be better than pharmacotherapy. It is also plausible that quitters may initiate the use of other tobacco products to quit smoking but sustain their use rather than quitting nicotine use completely after smoking abstinence has been reached. It can therefore be concluded that the use of pharmacotherapy, coupled with technological or human support, will increase quitting success rates.

Data availability statement

The raw data supporting the scoping review and conclusions mentioned are available upon request. Please contact for more information.

Disclosure

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ISL has a decade of experience in regulatory affairs and analytical testing, offering innovative solutions to ensure that products are compliant with regulations, directives, and standards. ISL works in partnership with customers, providing expert consultancy and analytical services to other industry members. ISL and CDP have worked closely on product design and public health initiatives for nearly a decade.

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Abbreviations

ABBREVIATION	WORD
5As	Ask, Advise, Assess, Assist and Arrange
ANVISA	Agencia Nacional de Vigilancia Sanitaria
CBT	Cognitive Behavioral Therapy
ENDS	Electronic Nicotine Delivery Systems
FCTC	Framework Convention on Tobacco Control
GA	Global Action to End Smoking
NPs	Nicotine Pouches
NRT	Nicotine Replacement Therapy
5R's	Relevance, Risks, Rewards, Roadblocks, and Repetition
WHO	World Health Organization

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Further reading and viewing

If you would like to read more about Cambridge Design Partnerships work with Global Action to End Smoking (previously named: Foundation for a Smoke-Free World); other articles, videos, and reports are available online.



Impediments to tobacco harm reduction in LMICs: The ENDS adoption journey



Why do people continue to smoke, even when they're aware of the risks?



Could availability of ENDS encourage smokers to consider quitting?



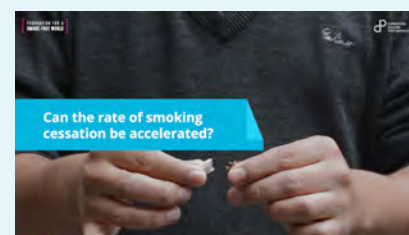
Can tobacco control regulations help reduce smoking prevalence?



Could ENDS replace traditional cigarette use?



Five approaches to improve smoking cessation outcomes and reduce tobacco harms globally



Can the rate of smoking cessation be accelerated?



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