

Overcoming barriers to disseminate effective smoking cessation treatments globally

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Abstract

Purpose – *The purpose of this paper is to review the barriers in the dissemination of effective smoking cessation treatments and services globally. Offering tobacco users help to stop using tobacco is a key demand reduction measure outlined under Article 14 of the World Health Organisation (WHO) Framework Convention on Tobacco Control (FCTC). Implementing Article 14 can reap great dividends for the billion plus tobacco users around the world and their families, friends and societies.*

Design/methodology/approach – *A review of the status of the global implementation of Article 14 using available literature on smoking cessation products, services and national guidelines. Discussing innovative approaches being currently explored in South Asia that can lead to faster adoption and implementation of Article 14 globally.*

Findings – *Major gaps remain in cessation products' availability and resource allocation for cessation services globally. Current licensed products are falling short on delivering and sustaining smoking cessation. Innovation in cessation products and services needs to build on learnings in nicotine pharmacokinetics, behavioural insights from consumer research and tap into 21st century tools such as mobile based apps. National implementation of FCTC's Article 14 needs to follow guidelines that encourage integration into existing health programmes and health-care practitioners' (HCPs) upskilling.*

Originality/value – *Smoking cessation is a desirable health outcome and nicotine replacement products are a means of achieving cessation through tobacco harm reduction. E-cigarettes are sophisticated nicotine replacement products. Innovation is urgently needed to fill the gaps in smoking cessation products and services, and for converting global policy into local practice. In low- and middle-income countries (LMICs), HCPs' knowledge, attitudes and practice regarding tobacco use and cessation may hold the key to rapidly scaling up cessation support and delivery to achieve FCTC objectives sooner. Additionally, HCPs can play an important role in offering smoking cessation support in existing national health programmes for TB, cancer screening and maternal and child health. Also, widely prevalent smartphone devices may deliver smoking cessation through telemedicine in LMICs sooner, leapfrogging the hurdles of the existing health-care infrastructure.*

Keywords *FCTC Article 14, Smoking cessation, Tobacco dependence treatment, Nicotine replacement therapy, Tobacco harm reduction, Cessation guidelines, Health-care practitioners, Policy-practice gap*

Paper type *General review*

Introduction

Smoking is a leading cause of preventable death and disease globally. Smoking-related diseases include heart disease, chronic obstructive pulmonary disease and cancer. "Smoking cessation" or "quitting smoking" is to completely stop smoking combustible cigarettes. Nicotine is the addictive element of tobacco, but it is the tar and other toxicants in tobacco smoke, not nicotine, that cause most of the harm. The principle of tobacco harm reduction, where adult smokers eventually completely switch to non-combustible nicotine-containing products, can be applied to achieve and maintain cessation (adapted from ASH UK).

(Information about the authors can be found at the end of this article.)

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Expression of concern: The publisher of the journal *Drugs and Alcohol Today* is issuing an Expression of Concern for the following article Patwardhan, S. and Rose, J.E. (2020), "Overcoming barriers to disseminate effective smoking cessation treatments globally", published in *Drugs and Alcohol Today*, Vol. 20 No. 3, pp. 235-247, to inform readers that credible concerns have been raised regarding the editorial process for this article. An investigation is ongoing and is currently unresolved. Further information will be provided by *Drugs and Alcohol Today* as it becomes available.

Quitting smoking can reverse the excess risk borne by smokers, and the lower the age at quitting, the greater is the degree of excess risk that is lost. Smokers who quit before the age of 45 will shed most of the excess risk of smoking and gain on average 9–10 years of life, whereas those who quit later will lose about half of their excess risk from smoking, gaining 4–6 years of life expectancy (Box 1). Thus, it is important not only to stress the importance of quitting smoking, but the importance of doing so at a young age (Jha *et al.*, 2013). Today's tobacco users will make up the majority of future tobacco-related deaths, which will disproportionately affect LMICs (Yach *et al.*, 2014). Providing access to and encouraging the use of effective cessation interventions greatly increases the likelihood of successfully quitting tobacco.

Box 1

Health benefits of quitting (US Surgeon General's, 2020 Report, January)

- Quitting smoking reduces the risk of premature death, improves health and enhances quality of life. Quitting can add back as much as 10 years to life expectancy.
- Quitting smoking lowers the risk for many adverse health effects, including poor reproductive health outcomes, cardiovascular diseases, COPD and 12 types of cancer.
- Quitting smoking is also beneficial for people who have already been diagnosed with coronary heart disease or COPD.
- Quitting smoking reduces the costs of smoking for people who smoke, health-care systems and society.
- While quitting earlier in life yields greater health benefits, quitting smoking is beneficial to health at any age. Even people who have smoked for many years or have smoked heavily will benefit from quitting.

Reducing demand for tobacco through cessation support is one of the World Health Organisation (WHO) Framework Convention on Tobacco Control's (FCTC) core demand reduction strategies. (WHO, 2003 FCTC). Article 14 of the WHO FCTC and its Guidelines call upon Parties to implement a series of measures to help tobacco users to quit. (FCTC Article 14 Guidelines, COP4, 2010). The guidelines call for the following actions:

- encourage Parties to strengthen or create a sustainable infrastructure that motivates attempts to quit, ensures wide access to support for tobacco users who wish to quit and provides sustainable resources to ensure that such support is available;
- identify the key, effective measures needed to promote tobacco cessation and incorporate tobacco dependence treatment into national tobacco control programmes and health care systems; and
- urge Parties to share experiences and collaborate to facilitate the development or strengthening of support for tobacco cessation and tobacco dependence treatment.

Offering help to quit tobacco use is also one of the six components of the MPOWER policy package from the Tobacco Free Initiative of the WHO intended to assist in the country-level implementation of effective interventions to reduce the demand for tobacco (MPOWER, 2008) (Table 1).

With more than a billion smokers globally, the importance of supporting, enabling and sustaining cessation cannot be overemphasised. A review of available cessation aids and

Table 1 Six components of MPOWER

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

services, and the national implementation of Article 14 guidelines is warranted to understand what bottlenecks may be impeding the delivery of effective tobacco dependence treatments globally.

A product and services innovation gap

Smoking cessation is an outcome. Depending on the smoker, there are many different paths, often complementary, to achieving this outcome. These are briefly reviewed in this section.

Smoking cessation aids. There are seven smoking cessation medications that have been approved by the US Food and Drug Administration (FDA) (Table 2) (Cahill *et al.*, 2014). Five of these treatments are forms of nicotine replacement therapy (NRT) including nicotine patch, gum, lozenge, inhaler and nasal spray. Additionally, two pills are available: varenicline (Chantix/Champix) and bupropion (Zyban/Wellbutrin). Among US smokers who make a quit attempt, 29.1% use NRT, whereas only 7.9% use varenicline and 2.4% use bupropion (Babb *et al.*, 2017). A nicotine sublingual tablet and nicotine mouth spray are other forms of NRT available outside of the USA (Rigotti, 2019).

The UK has a wider choice and access to NRT than the USA, with mouth spray (Nicorette Quickmist) and inhaler (Voke) licensed for general sales (MHRA).

At first inspection, this may appear to be a reasonable choice of medications for smoking cessation. In real world settings, however, clinicians face a significant problem when choosing a medication to help a patient quit smoking. E.g. Smoking rates among women who smoke during their pregnancy remain high even in countries such as the UK where a wide range of tobacco control measures are already implemented. Low uptake and success of smoking cessation treatments and services by women who smoke during pregnancy remains an unaddressed challenge (Smokefree in Pregnancy Challenge Group, 2019). This is compounded by the fact that there is limited clinical trial data on varenicline's safety for use among pregnant women who smoke (Tran *et al.*, 2020).

Table 2 Smoking cessation medications (OTC = over-the-counter, Rx = prescription only)

<i>Medication</i>	<i>Six-month abstinence</i>	<i>Tolerability</i>	<i>Clinical use</i>
Nicotine replacement therapy (NRT)	17.6% ^a	8% have nausea, dizziness and tachycardia, ^b 1% have an adhesive allergy. ^b	Patch, gum, & lozenge are OTC. Inhaler & nasal spray, Rx only ^{c, d}
Bupropion- dopamine + norepinephrine increase	19.1% ^e	Insomnia (24–42%), dry mouth (6–28%), nausea (9–13%), & seizure 0.1% (almost all > 300 mg/day) ^{e-f}	For most smokers, bupropion is well tolerated. Rx only ^{g-k}
Varenicline- nicotinic receptor partial agonist	27.6% ^e	57% nausea ^l , 37% vivid dreams/ insomnia ^m , 1% mood disturbance ⁿ , & suicidality infrequent ^o	Providers are reluctant to use it due to side effects. Rx only ^{n-p}

Notes: ^aCahill *et al.* (2014); ^bBabb *et al.* (2017); ^cHughes *et al.* (2003); ^dRose *et al.* (2009); ^eSchnoll *et al.* (2009); ^fWilkes (2008); ^gDavidson (1989); ^hFiore *et al.* (1999); ⁱFant *et al.* (2009); ^jHolm and Spencer (2000); ^kDamaj *et al.* (2004); ^lStahl *et al.* (2004); ^mHalperin *et al.* (2009); ⁿHays and Ebbert (2008); ^oTonstad *et al.* (2010); ^pGonzales *et al.* (2006)

All smoking cessation medications have an efficacy of under 20% at six months, except for varenicline. The EAGLES trial showed that varenicline did not have significantly higher incidence of severe neuropsychiatric side effects compared to NRT or bupropion (Anthenelli *et al.*, 2016). However, varenicline has a higher incidence of other non-neuropsychiatric side effects such as nausea (Tonstad *et al.*, 2010; Update, 2017), with as many as 53% of patients stopping treatment early, primarily due to those side effects (Gonzales *et al.*, 2006; Stahl *et al.*, 2004). Inasmuch as clinicians only prescribe varenicline for 7.9% of quit attempts, there is a “gap” in our current selection of smoking cessation medications. Namely, we need a medication that is more effective than NRT or bupropion but does not have the side effect profile exhibited by varenicline. If such a medication was found, it would almost certainly be widely prescribed by medical providers.

When trying to quit, smokers report missing the act of smoking, consisting of puffing on a cigarette and inhaling smoke, along with the accompanying taste, aroma and respiratory tract sensations elicited by nicotine and other smoke constituents. Some studies have found these sensory/behavioural components to be even more important than obtaining nicotine in the bloodstream in terms of satiating the desire to smoke. When these sensations are missing, the ability of nicotine to alleviate craving is attenuated (Rose, 2006).

Conversely, providing these sensory and behavioural aspects leads to reduced craving and potentially offers effective support for a cessation attempt (Rose *et al.*, 2003). In this regard, e-cigarettes represent a unique and promising approach to smoking cessation, because unlike other cessation approaches, they replace the sensory/behavioural, or “habit” component of the addiction. Indeed, clinical trials have supported the efficacy of e-cigarettes, and a recent clinical trial reported that long-term (one year) smoking abstinence rates were approximately twice as high as with state-of-the-art combination NRT: 18 vs 9.9% (Hajek *et al.*, 2019). Interestingly, 80% of the successfully abstinent smokers were still using e-cigarettes at the one-year follow-up (vs 9% of the NRT group), suggesting that their nicotine dependence had been successfully transferred from cigarettes to the non-combustible e-cigarette alternative. Given this emerging evidence, combined with the fact that e-cigarettes provide nicotine replacement along with meeting behavioural needs of smokers, these products represent a sophisticated form of nicotine replacement therapy, though they are not medically licensed as such.

The long-term health risks of consuming e-cigarettes are not known; however, their potential as a tool for smoking cessation and relapse prevention is promising (Notley *et al.*, 2018). There are currently no medically licensed e-cigarettes on the market anywhere globally; however, in countries such as the UK where e-cigarettes are regulated and monitored for any adverse effects and youth uptake, e-cigarettes are now the most popular method for quitting smoking (Public Health England, 2019). According to analysis of data from the UCL Smoking Toolkit Study, it was estimated that in 2017, around 50,700 to 69,930 smokers had quit smoking combustible tobacco by using e-cigarettes, who would otherwise have carried on smoking (Beard *et al.*, 2019). As the e-cigarettes are sold and bought as consumer goods, they do not incur an additional cost to the health services.

Combination treatments. Cigarette smoking is an addiction that consists of multiple behavioural and pharmacological components. Hence, it is unlikely that a single treatment can address all of the needs of smokers attempting to quit. A number of combinations treatments have shown promise and recommended.

It is now proven that using combinations of nicotine replacement therapies can increase the likelihood of quitting. Combining short- and long-acting forms of nicotine replacement therapy increases smoking cessation compared with using single forms of nicotine replacement therapy (US Surgeon General's, 2020 Report, January). E.g. using quick-acting nicotine mouth sprays combined with longer-acting nicotine patches can provide immediate (within a minute) as well as sustained (over hours) craving relief, respectively.

Relapse to smoking remains a significant issue over many months, and even years, after an initial quit attempt. One study found that, at an average of 4.3 years follow-up, smoking abstinence rates using NRT were only 7.2% above placebo (Etter and Stapleton, 2006). Another illuminating study (Schnoll *et al.*, 2010) found that providing NRT for 24 vs 8 weeks delayed smoking relapse during the 24 weeks of treatment. When NRT ended, however, relapse ensued and seven-day point abstinence rates at one year were not significantly different between the two groups. Studies following up smokers who have been abstinent for at least one year have found that about one third to one half subsequently relapse back to smoking over the subsequent 5–10 years (Nyakutsikwa *et al.*, 2019). Thus, a case can be made for transferring nicotine dependence from cigarettes to a less harmful alternative until the rate of relapse has fallen to a low level, which appears to be much longer than one year.

Behavioural counselling and smoking cessation services. While the majority of smokers attempt to quit either without any assistance at all (“cold turkey”), or with over-the-counter nicotine replacement therapies and e-cigarettes, combining these with behaviour therapy has been shown to increase the likelihood of success. Indeed, behavioural treatments, either in group or individual formats, increase rates of smoking abstinence, with greater enhancement in abstinence rates as more sessions/hours of treatment are provided (Lancaster and Stead, 2017). Adding behavioural treatment to pharmacotherapy increases rates of abstinence beyond either treatment approach alone (Rovina *et al.*, 2009; Hiscock *et al.*, 2013). The challenge is to provide behavioural support in a user-friendly fashion so that smokers will avail themselves of treatment, for example, by developing remote systems for providing smoking cessation counselling. Telephone counselling has been shown to produce a modest increase in cessation of approximately 1.3–1.4 times that of a control condition that does not provide such counselling (Stead *et al.*, 2006). A number of quit-smoking apps for smart phones have been developed, but thus far evidence for their efficacy is limited (Haskins *et al.*, 2017; Regmi *et al.*, 2017).

In this context, till recently, the UK’s Stop Smoking Services were unique for the scale and universal coverage they achieved (Action on Smoking and Health, UK, 2019). The services offered an evidence-based cafeteria approach, providing a range of stop smoking products and in-person as well as online advice. The attendance and successful quit attempts supported at the stop smoking services peaked in 2011 at around 100,000 successful cessations (at four weeks). However, the number fell to 35,000 in 2017 corresponding with a series of funding cuts and reorganisation of the stop smoking services away from the National Health Services into the local authority-run services (Frontier Economics, 2019). This experience highlights the challenges with sustaining a state-funded national cessation service.

A 2018 review of globally available smoking cessation products and services (EY-Parthenon, 2018) summarises challenges to and opportunities for achieving smoking cessation and preventing relapse (Box 2):

- Current solutions can deliver successful one-year cessation in only 13–23% of smokers who use them.
- The pipeline for drugs and medical devices will not deliver a breakthrough over a 5–10-year horizon.
- The App space has seen a lot of activity, and clinical trials are ongoing to deliver some evidence on efficacy.
- E-cigarettes are seeing a lot of activity, but their role in cessation must be evaluated (trials are ongoing).
- To deliver impact in the short to medium term, interventions are required to make the most of these existing solutions (e.g. though combinations, personalization, etc.).
- In the medium to long term, more incentives are required to find novel solutions.

In addition, the paucity of cessation studies on, treatment protocols for and services tailored to the needs of smokers in certain demographics (gender, mental health, LGBTQ, indigenous populations, etc.), risks widening the health inequality gap (Glover *et al.*, 2020; Solomon, 2020).

Market access and affordability gap

For effective implementation of Article 14 at a national level, recommended approaches include brief advice at primary care level, national toll-free tobacco quit lines, cost-covered nicotine replacement therapies and the use of digital and mobile technologies to empower those who want to quit.

According to the 2019 WHO report on the Global Tobacco Epidemic, *Offer Help to Quit Tobacco Use*, there are market forces and economic factors playing a key role in the availability of smoking cessation products and services in many countries.

From Table 3, it is evident that NRT is not available in 62 of the 195 countries surveyed. Based on the authors' experience, Varenicline is even less available and accessible given its higher price and single global patent holder (Lee *et al.*, 2019). It is also noteworthy that just over 25% of countries partially or wholly cover costs of cessation treatments and services.

Article 14 and health-care practitioners: policy and practice gap

Implementation of a full package of cessation services at best-practice levels remains remarkably uncommon in most countries. According to the 2019 WHO Report on the Global Tobacco Epidemic, as of 2018, out of the 195 countries surveyed, only 23 countries (including only six middle-income countries and one low-income country) offered comprehensive cessation support for tobacco users who were seeking help to quit (WHO, 2019a). A deeper analysis of the implementation of Article 14 across the 195 countries shows the wide gap between policy and practice.

Health-care practitioners (HCPs) remain largely excluded and neglected in the fight against tobacco, starting with their own consumption of tobacco. Addressing tobacco use by HCPs in national treatment guidelines and provision of specific programmes promoting cessation among them are a key recommendation laid out in the Article 14 guidelines. The review of 34 national guidelines available online showed that the majority did not include statements that HCPs should not use tobacco and only 12% recommended cessation support for HCPs who use tobacco.

The overall estimated prevalence of tobacco use among HCPs between 2000 and 2014 was 22%, ranging from 7% in nurses in LMICs to 27% in nurses in UMICs, and from 17% in doctors in high income countries to 25% in doctors in UMICs. Male doctors in LMICs had the highest prevalence, 35 and 45%, respectively. Female nurses in middle and high income countries also had elevated prevalence, 24 and 21%, respectively (Kapka *et al.*, 2019).

As shown in Table 4, fewer than half the countries surveyed have developed clinical guidelines on cessation. Moreover, with the exception of some European countries training in tobacco

Table 3 Data derived from WHO report on the Global Tobacco Epidemic, 2019

<i>Region</i>	<i>No. of countries</i>	<i>NRT NOT available</i>	<i>Cost covered (partial or wholly) for NRT (where available)</i>
Africa	47	23	9
The Americas	35	10	12
South East Asia	11	6	3
Europe	53	9	12
Eastern Mediterranean	22	8	8
Western Pacific	27	6	12
Total	195	62	56

cessation or brief intervention is rarely included in health-care curricula or training of primary care providers. This is reflected in the practice of those HCPs, with only 36 out of 195 countries reporting that tobacco use is routinely recorded on medical records. So even having clinical guidelines at a national policy level is only translated into less than half of those countries' doctors and other HCPs recording smoking status of their patients. It is unlikely then, that these HCPs will proactively offer advice or follow up on smoking cessation in their patients.

Importantly, HCPs' knowledge of tobacco cessation guidelines and an understanding of tobacco harm reduction principles remains poor. There still persists confusion among HCPs on nicotine's safety profile and role of NRT. Previously published research on attitudes of HCPs from Sweden and the UK towards nicotine pointed to gaps in their understanding the relative safety profile and potential of alternative nicotine products in harm reduction (Patwardhan and Murphy, 2013). The authors' latest research in the UK and India (unpublished, 2020) suggests that myths persist among HCPs about the role of nicotine in the harms from tobacco smoking, where more than 50% of the sampled HCPs wrongly believing that nicotine from tobacco smoke causes cancer. This can become a barrier when it comes to one of the main pillars of Article 14 delivery: prescribing NRT for smoking cessation.

Discussion

The FCTC is included in the sustainable development goals (SDGs) recognised as one of the means of implementation to reach the overall health goal (SDG3) and a target on non-communicable diseases (NCDs) (WHO, 2015 From MDGs to SDGs). Enabling the currently billion plus smokers globally to quit smoking can significantly contribute to achieving the SDGs. Achieving smoking cessation is a desirable health outcome for those dependent on tobacco. However, innovation is urgently needed to achieve and maintain cessation at scale and at affordable costs globally.

Role of health-care practitioners

Nicotine replacement therapy products were the first and still are the only medically licensed tobacco harm reduction options available for smoking cessation. WHO's emphasis on bringing nicotine replacement therapy products on the essential medicines list (WHO, 2019b Model List; Kishore *et al.*, 2010) was important in this context. UK's Public Health thought leaders' understanding of tobacco harm reduction and nicotine's safety profile played an important role in enhancing the access to nicotine replacement therapies for smoking cessation; e.g. the UK's medicines agency (MHRA) extended the indications for licensed nicotine replacement therapy for temporary abstinence, cutting down to quit and harm reduction. This decision was a result of clarity of goal of achieving and sustaining smoking cessation and using adequate replacement

Table 4 Data derived from WHO (2019a) report on implementation of article 14 in 195 countries

Region	No. of countries	Country has national tobacco cessation clinical guidelines: YES	Training in tobacco cessation is included in health-care degree curricula or primary care providers are regularly trained in brief tobacco interventions: YES	Tobacco use status of patients is routinely recorded on medical records: YES
Africa	47	11	1	3
The Americas	35	15	9	6
South East Asia	11	6	4	3
Europe	53	32	23	16
Eastern Mediterranean	22	9	6	5
Western Pacific	27	9	6	3
Total	195	82	49	36

nicotine for as long as necessary to prevent relapse (MHRA, 2010). This decision had the potential to give confidence to HCPs on their NRT prescribing practices.

However, the emerging data from the UK, USA, Bangladesh and India suggests that HCPs have not been adequately upskilled on nicotine's safety profile, its role in tobacco harm reduction and applying that to their clinical practice. This can be a significant barrier to their ability to provide practical cessation advice to their smoker patients. E.g. believing that "nicotine in tobacco causes cancer" (Patwardhan and Murphy, 2013; unpublished research) can be a significant barrier to the HCPs prescribing adequate NRT for long enough to achieve and sustain cessation. To convert WHO's implicit tobacco harm reduction policy into practice requires a concerted cessation training programme in HCPs' education, starting with medical curricula and continuing into professional development throughout their careers. Our work in South Asia is designed to address this unmet need.

In India, the authors are involved in preparing a systematic training programme for HCPs to upskill them using global best practice applied to locally available cessation treatments. This will involve creating nationally relevant cessation protocols and guidelines, including those for smokeless tobacco products. The programme will be first piloted, monitored and assessed across selected hospitals and research centres. On validation of the content and confirming the fitness for purpose, it will be rolled out over the next five years to the millions of HCPs practising in the urban as well as rural areas of India, providing practical tools for opportunistic intervention as a part of providing holistic health care to their patients. Learnings and best practice from this programme will also be shared with neighbouring South Asian countries through knowledge transfer collaborations with healthcare institutions.

Role of innovation in low cost products and service delivery

Insights from behavioural studies on smoking patterns and barriers to access are critical for informing the design of innovative nicotine replacement products and cessation services. Cost and affordability are an important consideration, especially for the remaining smokers in the developed world and for the majority of smokers in LMICs. In that context, low-cost alternatives to proven cessation treatments need to be actively evaluated and promoted. Cytisine is a good example of such a low-cost cessation medication. Cytisine bears some structural similarity to varenicline and has a similar pharmacologic profile in terms of action at nicotinic cholinergic receptors. It has similarly shown promise in smoking cessation treatment. Like varenicline, it yields a somewhat higher abstinence rate than NRT and is also associated with a higher incidence of nausea (Walker *et al.*, 2014). Its cost is much lower than other pharmacotherapies and thus may have special value for low-income smokers who do not have adequate preventive health care coverage.

Regarding alternative nicotine products, manufacturers need to work with policymakers to create and comply with regulatory frameworks that ensure consumer safety and quality assurance and prevent youth uptake. This is particularly true in the case of e-cigarettes and nicotine pouches, both product categories with a promising role in smoking cessation due to their harm reduction potential.

Mobile-based cessation apps provide great promise, but as noted earlier, have not been tested rigorously enough or have not yet delivered on the promise of population level cessation success. In LMIC countries such as Bangladesh with 19.2 million smokers (WHO, 2017a GATS Bangladesh) with wide mobile coverage and smartphone access, there are opportunities to leapfrog the cessation services gap. The authors are currently involved in trialling mobile-based smoking cessation apps in Bangladesh, supported by HCPs through videoconferencing, prescribing NRT products and offering behavioural incentives. The scale, reach and potential impact of such trials may offer an innovative, holistic approach and low-cost solution to achieving cessation in LMICs.

Tobacco use negatively impacts outcomes for TB, pregnancy, cardiovascular disease and cancer (WHO, 2019a). Health ministries in LMICs may struggle to allocate dedicated nationwide resources to tobacco cessation. However, HCPs involved in delivering existing well-funded vertical programmes for TB, maternal and child health and cancer screening could benefit from being trained in tobacco cessation – covering smoked as well as smokeless tobacco.

Limitations

In this paper, we use smoking cessation treatments and services as an example of tobacco dependence treatments and services. Over and above smoking related death and disease, LMICs in Asia and Africa are also negatively impacted by the disease burden arising from oral (smokeless) tobacco use. We note that smoking cessation treatments may be used for oral tobacco use cessation – however do not have solid scientific evidence and clinical guidelines to support that practice (Nethan *et al.*, 2018). The prevalent systemic and practical challenges remain in implementing Article 14 recommendations in LMICs, irrespective of the type of tobacco product dependence that needs addressing. The challenges are amplified when viewed from a gender lens – e.g. the unaddressed use of smokeless tobacco among women in South Asia (WHO, 2017a GATS Bangladesh; WHO, 2017b GATS-2 India) and unavailability of tailored cessation support risk widening the gender-related health-inequality gap among women even further in these countries.

Conclusions

Article 14 remains one of the most neglected tools of demand reduction in the context of the FCTC.

Current available cessation products and services are suboptimal in their effectiveness. Cost and efficacy of current smoking cessation medications on the market is an impediment to availability, accessibility and cessation success in LMICs. This is compounded by the fact that in countries such as India the predominant form of tobacco consumption is oral smokeless tobacco, with a large proportion of women users. Usage of oral tobacco during pregnancy is correlated with poor health outcomes for the mother and child. These are currently largely unaddressed and widening gender and health inequality. Innovation in tobacco cessation treatment and service delivery has the potential to reduce the gender and health inequality arising out of a disproportionately large number of women who use oral tobacco compared with those that smoke tobacco.

In countries where other tobacco control measures (retail display ban, graphical health warnings, plain packaging, incremental tax measures) from the FCTC are applied, tobacco dependence treatment provision is either patchy at a national level or not keeping up with the emerging evidence base. In LMICs with large numbers of tobacco users (e.g. India, Bangladesh, China) availability of pharmacotherapy products and smoking cessation services remains very low or non-existent. Unlike the UK and the EU, e-cigarettes are either banned or not regulated in most LMICs, thus denying a wider range of harm-reduction-based cessation options.

Providing adequate policy level support to establishing and resourcing cessation services in developed countries as well as LMICs is key to eliminating harms from tobacco. Concrete action is urgently needed to place cessation into all adult clinical services starting where need is critical: maternal child health, mental health, TB, cancer and heart/lung clinics. Trialling mobile-enabled telemedicine-based cessation services may open low-cost and scalable alternatives for LMICs.

HCPs should be at the frontline of delivering Article 14 recommended guidelines. Knowledge, attitude and practice among HCPs regarding their own tobacco use as well as their patients' tobacco use needs careful studying and intervention. Compulsory HCP

training on advances in cessation treatments and services has the potential for achieving the widest scale and impact for eliminating harms from tobacco.

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