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Scoping review of existing evaluations of smokeless tobacco control policies: What is known about countries covered, level of jurisdictions, target groups studied and instruments evaluated?

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Scoping review of existing evaluations of smokeless tobacco control policies: What is known about countries covered, level of jurisdictions, target groups studied and instruments evaluated?

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Abstract

Objective – The implementation of smokeless tobacco control policies lags behind those for smoking. This scoping review summarises the studies that evaluated public policies on smokeless tobacco regulation (SLT) and provides an overview of the jurisdictional level, target groups and policy instruments.

Methods – Seven databases were systematically searched for studies reporting on public policies regulating SLT. All studies were independently screened by two reviewers. Data extraction was performed using a predefined extraction form. Extraction was replicated for 10% of the identified studies for quality assurance. A narrative synthesis of the included studies was used to analyse and interpret the data. The protocol was published beforehand with the OSF.

Results – 40 articles comprising 41 studies were included. Most of the studies reported in the articles were conducted in the USA (n=17) or India (n=14). Most studies reported outcomes for students (n=8), retailers/sellers (n=8) and users/former users (n=5). The impact of public policies on smokeless tobacco use in general was most frequently assessed (n=9), followed by the impact of taxes (n=7), product bans (n=6), sales/advertising bans near educational institutions (n=4) and health warnings (n=3) on consumer behaviour.

Conclusions – There are major gaps in the evaluation of smokeless tobacco regulation studies that need to be filled by further research to understand the observed outcomes. WHO reporting on FCTC implementation should be linked to studies evaluating smokeless tobacco control measures

at all levels of jurisdictions and in countries that are not members of the WHO FCTC or do not provide data.

Keywords: Smokeless tobacco, tobacco control policy, national control policy, policy evaluation, WHO FCTC, policy implementation

Implication

Large gaps in the evaluation of SLT control policies exists. For some countries, WHO FCTC evaluations are available for different levels of jurisdictions. In countries with a strong federal structure, there is a lack of data that goes beyond the national level to provide a more detailed look at compliance, indirect effects or implementation gaps. More research is needed at all levels of jurisdictions, that add to the work of the WHO to understand what works for which target group, how the different levels of jurisdiction interact, how the real-world context can be incorporated, and what indirect effects may occur.

INTRODUCTION

Smokeless tobacco (SLT) is used by more than 300 million people worldwide[1, 2]. The geographical distribution of SLT use varies widely. While most SLT users (82 %) live in South and South-East

Asia, SLT is also widespread in Central Asia, the Scandinavian countries, North America and many African countries (e.g. Nigeria, Ghana, Algeria, Cameroon, Chad, Senegal, Sudan and South Africa)[3, 4]. SLT use is a risk factor for cancers of the head and neck[5] and is associated, for example, with cardiovascular disease and adverse reproductive outcomes such as low birth weight, preterm and stillbirths[4, 6]. According to the Global Burden of Disease study, there were 55,600 deaths (95% UI 43,100-68,800) due to SLT in 2019, of which 46,000 (35,500-58,000) were in South Asia[7].

The WHO Framework Convention on Tobacco Control (FCTC) was adopted by the World Health Assembly in 2003 and was open for signature between June 2003 to June 2004, during which time 168 countries signed the treaty[8]. It provides a comprehensive strategy to combat the tobacco epidemic, including SLT (Appendix 5)[9]. The FCTC is WHO's first global public health treaty[10]. It is legally the international community's most powerful tobacco control instrument[11]. The Convention is binding on countries through ratification, acceptance, approval, formal confirmation or accession[12]. The WHO FCTC must be transposed into national law, applied and enforced to become part of the national law of a sovereign state. This includes comparing existing legislation with the treaty provisions, examining administrative structures and adapting them where necessary, and developing administrative and technical guidance for its application[13]. Currently, 182 Parties, whose populations represent 90% of the world's population, have signed the Convention[14]. Existing reviews of the impact of the FCTC indicate promising approaches to reducing tobacco use[9, 15]. Although SLT products fall within the policy framework of the WHO FCTC, they have not received the same priority as tobacco among FCTC Parties. Only 34 out of 180 Parties (as of 2019) tax or report taxing SLT products, six Parties measure SLT product content and constituents, and 41 of the Parties require pictorial health warnings on products. Only a few Parties collect or present data on smokeless tobacco use through global or national surveillance mechanisms (e.g. Global

Tobacco Surveillance System and WHO STEPwise) or have comprehensive bans on advertising, promotion or sponsorship of SLT[4].

The WHO FCTC has been the subject of several studies, both for smoking and SLT, e.g. by Chung-Hall et al., Mehrotra et al., Siddiqi et al. and Gravely et al.[4, 9, 16, 17]. These papers provide deep insights into the implementation of the WHO FCTC. They describe whether FCTC measures have been implemented at national level for SLT. However, they do not provide information on whether these measures have been evaluated. Furthermore, not all UN states have signed the Convention. Some Parties have signed the treaty but have not implemented it, e.g. the USA, Argentina, Cuba or Switzerland. Some Parties have not signed but ratified the Convention, e.g. Tajikistan, Bahrain and Zimbabwe. Other Parties have signed and ratified the Convention but do not report data to WHO on the status of their SLT responses (Table 1). For these countries, policy evaluation studies are one way to get an overview of the effectiveness of tobacco control policies. They summarise what data are available for which level of jurisdiction (state, county, city). This increases the explanatory power for the different policy instruments used depending on the underlying organisational structures and legal responsibilities. It provides an overview of tobacco control policy, which areas are covered, how target groups respond, what indirect effects (may) occur and what data gaps exist. Moreover, combining WHO reporting with data from sub-national levels (states, county, city) for countries reporting under the WHO system allows for a more detailed and nuanced understanding of compliance with the WHO FCTC Framework Convention in these countries.

This work adds to the existing literature. The aim of the scoping review is to summarise studies that have analysed government policies to control SLT use in order to fill the gaps in the WHO FCTC reporting system. The objectives are to identify: (1) countries for which studies evaluating public policies are available to complement existing WHO FCTC data, and (2) the level of

jurisdiction, population groups and instruments studied, and the impact on consumption behaviour reported in these studies.

METHODS

The scoping review follows a similar approach to a systematic review[18-21]. The Preferred Reporting Items for Systematic Reviews and Meta-Analysis: extension for Scoping Reviews (PRISMA-SCR and flow chart) were used to illustrate the flow of information through the different stages of the scoping review[22]. A study protocol was published in advance[23].

Search strategy and information sources

An information specialist advised on the search strategy. The search structure combined two concepts: SLT and public policy (Table 1, Appendix 1). Appropriate keywords, their synonyms and controlled vocabulary for relevant terms were used. The search syntax and vocabulary were adapted for subsequent searches in other databases on other platforms. The search strategy for Medline is available as a supplementary file (Appendix 1).

In November 2019, structured searches were conducted in the following electronic databases: Medline, PsychInfo, Science Citation Index, CINAHL, Econ.Lit, ASSIA and International Bibliography of the Social Sciences (IBSS). The reference lists of the included studies were searched by hand for additional citations. All results were exported to the literature management software EndNote for deduplication. The deduplicated results were imported into the Covidence systematic review management software to check title/abstract and full texts. All studies (title/abstract and full texts) were screened independently by two reviewers according to predefined criteria. Data extraction of all full texts was performed using a previously developed and tested extraction form. The extraction was repeated for 10% of the identified studies for quality assurance. Disagreements during the screening and extraction process were resolved by consensus.

Inclusion and exclusion criteria

The focus was on studies that evaluated the control of SLT at each level of jurisdiction to complement the knowledge collected for reporting on the implementation of WHO FCTC[4, 9, 17]. Our aim is to identify additional information to fill the gaps in reporting systems where data are not available. No restrictions were placed on the language or type of study. No review articles or modelling studies were included. Grey literature was not included due to lack of resources, e.g. ministerial reports, reports from international or social organisations.

We screened all included studies for reported affiliation, conflict of interest and funding to control for industry involvement. Only studies where the authors did not declare a conflict of interest or industry funding and where the authors were not affiliated with an industrial company were included.

Data extraction, coding and analyses

Studies were grouped by country, jurisdiction level (national, state, county, city), WHO FCTC articles and population groups studied. SLT policy effects were coded as positive, mixed or negative/no effect. The positive effect could be a reduction in consumption, a reduction in purchasing behaviour, knowledge of the regulations or compliance, depending on the instrument or focus studied. A mixed effect was coded if the results indicated a positive and a negative effect. No/negative effect was indicated if the results indicated that the policy had no effect or led to an increase in SLT use, or if a negative perception of the SLT control policy was reported.

If available in the included articles, information was provided on why the effect may have occurred or what influenced the outcome. Detailed information and the extraction sheet were published in

protocol[23]. The extraction sheet was tested a priori. A narrative synthesis of the included studies is used to interpret and analyse the data.

RESULTS

A total of 1,011 articles were found in the database search and 35 articles were found in the reference list check. After duplicates were removed, 925 articles were screened by title and abstracts and 197 articles were included in the full text screening. The inclusion criteria were met by 40 articles (Appendix 2.1 Flow chart). One article had to be excluded from the full text screening due to a lack of language skills within the research team, as it was written in Japanese, and is marked accordingly in the flow chart. Within the articles, Pimple et al. 2014 [24], Ohsfeldt et al. 1997[25], McClelland et al. 2015[26] and Mumford et al. 2005[27] report on two instruments; Patja et al. 2009[28] report on two countries: Finland and Sweden, which are treated separately. Thus, the 40 articles refer to 41 studies. None of the full texts included reported industry involvement.

Countries covered, policy instruments evaluated in terms of WHO FCTC articles, and level of jurisdiction

The most important characteristics of the included studies are listed in appendix 2. A large number of studies were conducted in the USA (n=17[25-27, 29-42]), followed by India (n=15[24, 43-56]) and Finland (n=3[28, 57, 58]). One study each reported results from Bhutan[59], Myanmar[60], Sweden[28], Bangladesh[61], Norway[62] and South Africa[63]. One study analysed different member states of the EU[64]. According to the World Bank 64 classification, twenty-two studies were conducted in high-income countries, one in an upper-middle-income country and 18 in lower-middle-income countries. One study reporting results from different EU countries is not included in the classification. Study designs used were cross-sectional (n=16[24, 30, 32, 35, 36, 40, 44, 48-52, 56, 57, 59, 60]), observational (pre-post studies

and interrupted time series analyses (n=5[33, 38, 41, 55, 61]), trend analyses (n=2[26, 42]), qualitative studies (n=3[47, 53, 64]) and mixed methods (n=2[45, 46]). Other designs used were snowball/network designs (n=1[43]) and quantitative designs (n=3, quasi-experimental comparison[39], randomised controlled trial[34], quantitative descriptive study[62]). Secondary data were used in nine studies, with Finland and Sweden counted as separate studies in the Patel et al. article[25, 27-29, 31, 37, 58, 63].

A summary of all legislation referred to in the included studies is provided in Appendix 3 (Appendix 3). In addition, Appendix 4 matches the identified legislation with the instruments examined in the studies (e.g. health warnings, taxation, prohibition) to the FCTC articles (Appendix 4). In the USA, the largest number of studies refers to the Comprehensive Smokeless Tobacco Health Education Act of 1986 and its amendment from 2009 by the Family Smoking Prevention and Tobacco Control Act (n=8). One study analysed fiscal developments based on the Children's Health Insurance Program Reauthorization Act (CHIPRA) (2009) (n=1), and eight articles reported evaluation findings that analysed various US federal tobacco control policies but did not cite the relevant laws (n=8). A large number of studies from India examined the Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act (COTPA) (2003) (n=8), Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations (2011) (n=6) and Goods and Services Tax (GST) (2017) (n=1). Articles on South Africa, Bhutan, Finland, Myanmar, Sweden, Bangladesh and Norway analyse the national SLT policies of each country. The article on ten EU Member States looks at compliance with three EU directives: the 2001 European Union (EU) Tobacco Products Directive (TPD), Directive 2008/118/EC and Directive 2003/33/EC 63.

Some studies that assessed national policies were less concerned with the specific instruments used, but examined in general terms the control of availability, access and promotion of SLT; awareness, attitudes and perceived barriers to policy implementation; application, enforcement and

compliance with existing national regulations; and their impact on the trends in SLT consumption[28, 44, 46, 59, 60, 63]. Studies that did not mention specific instruments are marked as 'general'. Other studies assessed the impact of specific policy measures, such as the impact of tax regulations on SLT consumption[25-27, 30, 33, 40, 55], ban on gutkha and pan masala[24, 45, 47, 48, 50, 53], health warnings on SLT packaging[37, 43, 61], ban on sales near educational institutions[24, 49, 51, 52], ban on flavoured products[38, 39, 41], smoke-free law, including analyses of litter indicating SLT use[25-27] and one study each for a display ban[62], packaging and labelling issues[56], sales and advertising[32], marketing and sales[42], modified retail outlet environments[34], sales to minors[36], product availability in pharmacies[35], banning snus[58] and snuff[57], public expenditure on tobacco control programmes in general[31] and taxes on products sold online across countries, and advertising bans within the EU[64] (Appendix 4 Table 4. 1 and 4.2).

Legislative power, and thus the level at which policy resides, differs between countries. While in the federally organised states such as the USA and India many policies have been evaluated at the city and state level, in the other states policies have been analysed primarily at the national level. The public policies included in the scoping review refer to the city level (n=16), followed by the national level (n=12) and the state level (n=10), the district/county level (n=2) and a supranational level (EU) (n=1).

Reported effects of SLT control policies

Reported results vary in terms of impact on SLT consume behaviour. Impacts are highly context-specific, ranging from positive impacts in one state to no impacts in another. For some policies, there are positive and negative impacts in one country (Appendix 4 Table 4.2).

The impact of individual measures varies and overlaps within categories and countries. Positive impacts, i.e. increased awareness or reduction in consumer behaviour, were reported for the

evaluation of general aspects of control measures such as knowledge, awareness and attitudes towards the policy as a whole. Positive effects were also reported for health warnings, taxes, the ban on flavoured products, the ban on snuff and the ban on display with regard to SLT.

Mixed effects were reported for general aspects of the policies, health warnings, sales near educational institutions, bans on gutkha/pan masala, packaging and labelling, sales and advertising, marketing and sales, changes in the outlet environment, sales to minors, product availability in pharmacies and cross-country online taxes, and advertising within the EU.

In the included articles, no or negative impacts were reported for general aspects, health warnings, bans on sales near educational institutions, bans on gutkha/pan masala, smoke-free laws and snus bans (Appendix 4 Table 4.2).

India

The general evaluation of COTPA, the health warnings (Article 11), the ban on advertising and sales near educational institutions (Articles 13, 16), packaging and labelling (Article 11), the ban on gutkha and pan masala, and the taxation of SLT products (Article 6) were examined.

Studies evaluating COTPA in general and analysing the impact of the implementation of the Goods and Services Tax (GST) on prices and its influence on SLT consumption found positive impacts[55].

The positive impacts of COTPA evaluation were discussed in terms of the population studied. The study population was older than 50 years and had more than 10 years of schooling. It was discussed that the higher awareness was probably due to a medium socioeconomic status and a good perception of second-hand smoke as harmful, and that higher education might be associated with a positive attitude towards COTPA[44]. The results, although positive, may only apply to this population group.

Mixed effects were reported for regulations banning guthka and pan masala. The regulations are well known, but the products, especially those produced locally; continue to be available to regular customers or in the black market at a higher price[24, 45, 47, 48, 50, 53]. Reddy et al. also reported that most gutkha consumers switch to other products (29.8% of the study population) and that newspapers were the main source of information about the ban (45.8% of the study population). However, they also reported high literacy levels in the study population[50]. Mixed effects were also found for the use of health warnings. While health warning regulations are followed for cigarettes, they are not followed for g gutkha[43].

No effects were found for the ban on sales near educational institutions. Although the ban is widely known, it is not implemented and rarely enforced. In addition, mobile vendors sell locally and are difficult to prosecute[24, 51, 52]. Furthermore, it is rarely known that violations can be reported. Selling to minors is accepted as a form of income. A study on COTPA among shopkeepers found that consumption and sales to minors are accepted, including as a form of income[46]. Barriers to the effectiveness of interventions mentioned include a lack of comprehensive information and awareness of the law, lack of economic alternatives especially for small-scale vendors, cultural acceptance of tobacco use, lack of political support, and the low priority given to combating SLT in general[46].

USA

In the USA, the ban on flavoured products had a positive impact on reducing SLT consumption (Article 9). The ban was accompanied by an extensive pre-ban information campaign and strong enforcement structures[38, 39, 41]. In addition, positive effects were found for high spending on public tobacco control programmes[31].

Mixed effects were reported for taxation, health warnings, advertising, sales and point-of-sale environment change measures, and evaluation of various tobacco control policies. In studies of whether subjects remembered health warnings, differences were found between income groups and education levels, with higher education levels associated with higher awareness. Awareness of health warnings about SLT was lowest among those with low education and low annual household income[37]. For the sales and advertising tools, point-of-sale advertising and the use of predominant tobacco advertising displays were reported to be more prevalent in shops more likely to be frequented by youth. Snus was also sold to underage purchasers[32, 36]. One study evaluated several national control measures and reported positive effects on tobacco uptake, but no effects on current users. It suggests a mix of tobacco control measures (higher taxes on smokeless tobacco, higher minimum legal age for purchasing tobacco products, strict licensing requirements for tobacco products, restrictions on giving away free samples of tobacco products, posting of signs indicating the minimum age for purchasing tobacco products) would be effective in reducing SLT use among adolescent males[29].

Three studies examining higher taxes on SLT use and surveying students and young adults (≥25) reported no impact on SLT use[26, 27, 40]. One study found an increase in SLT use among males in parallel with an increase in cigarette taxes[40]. Two other studies reported that a higher cigarette tax was associated with a decrease in cigarette use in general, but also with a shift and product switching to SLT[25, 30]. 69% of pharmacies in Massachusetts were licensed to sell tobacco products (all cigarettes, moist snuff (53%), snus (14%)). This represented 9% of licensed tobacco retailers[35]. The introduction of a tobacco-free pharmacy concept would impact the majority of pharmacies in Massachusetts, as a variety of products are currently sold in licensed pharmacies.

Other countries

For the other countries, the picture is similarly diverse. In Finland[28] and South Africa[63], the evaluation of national tobacco control policies produced positive results. Both reported a decrease in SLT consumption, in South Africa even without excise tax. However, in South Africa, an increase in consumption among black African women and a shift from the older to the youth population was noted[63]. In Norway, 98 % of shopkeepers complied with the ban on displaying snus[62].

Mixed impacts were reported for tobacco control policies in Myanmar and the online cross-country evaluation of the tax and advertising ban in the EU. Awareness of the policy is high in Myanmar. However, SLT products are still sold and there is a lack of awareness that non-compliance can result in a fine[60]. Although SLT products are banned in Finland, the prevalence of daily use among women is high and SLT products can be imported for personal use[28]. In the EU, taxation of tobacco products has been introduced and there is a ban on cross-border sales. However, cross-national online sales are still possible[64].

Population groups covered

The results of the evaluation of national policies to combat SLT consumption are diverse, and this also applies to the population groups included. The results are based on parts of the population (Table 3). The included studies report results for the following subgroups: students (n=8[26, 29, 31, 49, 52, 57, 58, 60]), retailers or vendors (n=8[32, 34, 36, 45, 46, 48, 50, 53]), user/former user (n=5[45, 47, 48, 50, 62]), shops, retail outlets (n=4[24, 42, 43, 56]), retail tobacco outlets (n=2[24, 42]), licensed pharmacies (n=1[35]) and school districts (n=1[51]). Sixteen articles did not further specify the population surveyed[26, 27, 30, 33, 35, 37-41, 54, 55, 59, 61, 63, 64]. Four studies reported results for males only[25, 27, 29, 47] or for both genders[28, 44, 50, 52]. Seventeen studies did not specify gender. Gender did not play a role in the 15 studies that

used household data or analysed the implementation of advertising bans in outlets and shops (Table 3, Appendix 2).

(3) Gaps in SLT policy evaluation research

The current and comprehensive assessment of the WHO FCTC is based on the WHO Global Progress Reports on FCTC Implementation 2012, 2014, 2016. 2018; WHO reports on the global tobacco epidemic 2013, 2015, 2017, WHO NCI Monograph, Global Tobacco Surveillance System Data (including results from the Global Adult Tobacco Survey, Global Youth Tobacco Survey, Global Professions Student Survey, Global School Personnel Survey), country, regional and global smokeless tobacco control reports, tobacco control laws and regulations, and searches of PubMed for WHO FCTC-specific key terms. They provide a comprehensive overview of the current situation and the availability of regulations and data. However, the data are highly aggregated.

Policy evaluation studies complement this overview by answering questions at the national or regional level with a focus on the application of regulations. However, the data are sparse. Data are only available for India, the USA, Bangladesh, Bhutan, Finland, Myanmar, South Africa, Sweden and Norway. The data are also limited to Articles 6, 8, 9, 11, 13 and 16, and some of the Articles are only partially covered, such as Article 13, which deals with advertising and marketing. Sponsorship and advertising are not covered in the included studies. Another example is Article 16, which specifically prohibits the sale of SLT products near schools. Policy evaluations in India found that the problem of mobile vendors and the role of disadvantaged neighbourhoods influence the impact of policies on certain groups. These findings need to inform public policy making at the designated legislative level. However, data are not available for every level of jurisdiction and every article.

No national, federal, regional or municipal policy evaluation studies are available for Articles 7, 12, 14, 15, 17, 18, 19, 21 and 22 (Table 4).

Policy evaluation studies are the only data sources for the USA, as it has signed but not ratified the WHO FCTC and is therefore not included in the WHO FCTC data reports.

DISCUSSION

The aim of this scoping review was to identify: (1) countries for which studies evaluating public policies are available to complement existing WHO FCTC data, and (2) the level of jurisdiction, population groups and instruments studied, and the impact on consumption behaviour reported in these studies. Most studies have been conducted in India and the USA, which is consistent with the work of Mehrotra et al.[4] and Siddiqi et al.[17]. However, there is a lack of studies evaluating SLT policies at national and subnational levels in countries with high SLT prevalence (e.g. Sri Lanka, Nepal, Mauritania or Sudan, Norway, Croatia). Only for seven countries (Bangladesh, Bhutan, Myanmar, South Africa, Finland, Sweden, Norway) we found policy assessments in addition to WHO FCTC evaluations. For Articles 6, 9, 11, 13 and 16, there is overlap between the WHO FCTC article evaluation reported by Mehrotra et al. and the studies identified in our work[4]. However, national evaluation studies have assessed the impact of tobacco control policies using waste analysis, which could be used to fill this gap[25-27]. In addition, not all data are available for the same country and jurisdiction level, which limits the transferability of results. Except for the US and India, the results are not based on different affected populations such as consumers/former consumers, people in different socio-economic groups, illiterate people or retailers. This made it difficult to make predictions about the acceptance and compliance of individual measures in different population groups. Preliminary findings on how enforcement of the WHO FCTC might affect SLT sellers in Pakistan and their attitudes towards such measures can be found in a recently

published paper[65]. Such findings are necessary to be prepared for the direct and indirect effects that the introduction of strict SLT control policies might have[66]. Further studies on public policy are needed that analyse the application and enforcement of control measures and the interaction between international regulations and national, federal and regional responsibilities. Research is needed on the impact of public policies on consumption patterns, problem awareness and behaviour change. A recently published protocol[67] and the recent study published by Yadav et al. for India begin to fill these gaps[68]. Future research should also aim to analyse the role of industry participation in SLT public policy making.

The impacts found point to some interesting facts that should be considered in the development and evolution of policies to control SLT consumption and products. First, while higher taxation of tobacco products is an appropriate tool to reduce prevalence and consumption of tobacco products, product substitution should be considered for subgroups. Especially in countries with large local production (e.g. India) or cross-border purchasing habits (e.g. Finland), more information is needed on the perceptions and responses of different consumer groups, as well as on the impact and consequences of taxation, in order to align taxation with other instruments, such as strict licensing requirements for tobacco products, the display of signs indicating the minimum age for purchasing tobacco products, awareness-raising campaigns and campaigns to promote social norms and education. In addition, strong public support and enforcement capacity could strengthen regulatory approaches. Secondly, while policies may be widely known, external factors determine how regulations are administered and adhered to. For subgroups, e.g. people of low socio-economic status, lack of education, in deprived neighbourhoods, users and former users, shopkeepers and people who derive their income from the production, transport and sale of SLT products, education campaigns and support strategies should be discussed to promote compliance. However, to do this, more detailed data are needed to inform policy action.

Where smokeless tobacco regulation interacts with other policies, such as the regulation of 'gutkha' or 'pan masala' under the Food Safety and Standards Ordinance in India, such synergies should be harnessed and targeted.

Similar to previous work, the points indicate that policies need to be adapted and developed to suit the national and sub-national context. Simply transferring approaches and policy instruments may not work. While much data is available, it is fragmented, relates to different levels of jurisdiction, to different target groups, and usually addresses only one aspect of control measures rather than interacting systems. Data at all levels of the evidence ladder need to be combined in a meaningful way to cover all level of jurisdictions. The most vulnerable groups and especially indirect effects need to be considered across jurisdictions. Data on subgroups, minorities, indirect effects, high- and low-income people in relation to attitudes or health warnings need to be collected and combined. Evaluation data linked to the process of policy development and implementation would also allow adjustments to be made if the impact does not materialise or even if it would be necessary to terminate certain approaches.

LIMITATION

Although the work follows the systematic approach of the Joanna Briggs Institute[21] and reports according to PRISMA-ScR[22], there are limitations. Due to licensing restrictions, the Embase database was not included. In addition, studies published in languages other than English or German were not included in the data extraction. This affected one study that was reported separately in the flow chart. In addition, studies on individual interventions that do not refer to public policies were not included. We may have missed some studies due to limitations to our search strategy which was developed with our research librarian. For example, studies that did

not contain the specific search terms we used (e.g. regulation, control policy, public policy), the corresponding MeSH terms or controlled vocabulary (depending on the system used in the databases) in the title or abstract would not have been identified. We also did not include grey literature, as this would have exceeded the resources of the research team. Work from ministries and non-for-profit organisations is therefore not included as long as it has not been published in peer-reviewed articles. Future work will have to fill this gap, which will also have to inform discussions on the methodological approach to results obtained from scientific and non-scientific literature.

In order to exclude any industry-sponsored studies, we have checked all included studies with regard to the stated affiliations, conflict of interests and funding. However, the information is based on the standards applicable at the time of publication. We have to trust the authors and the journal standards on this point, as it was not possible for the research team to check the information due to limited resources.

Due to the heterogeneity of study methodology and the nature of scoping reviews, no assessment of risk of bias was undertaken. Effects are only reported narratively.

CONCLUSION

More national and sub-national data is needed to support the development of evidence-informed policies based on existing regulations. The interplay between WHO FCTC regulations and jurisdictional levels affected at all levels should be analysed to identify mutually reinforcing systems or gaps. Much work needs to be done to develop best practice toolboxes, benchmarking systems and a combination of measures to develop strong and effective policies to combat SLT.

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Contribution following CRediT taxonomy of contributors

Conceptualization, SF, ZK, HZ; Methodology, SF, ZK, HZ; Investigation, SF, ZK, AF, AF, JF, TK, SU; Resources, LC; Writing original, review, editing: SF, ZK, AF, AF, JF, TK, SU, DO, KS, ZH; Funding Acquisition, SF, HZ, ZK, KS.

Competing Interests

None

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Data availability statement

Not applicable. All related data are attached to the publication as appendix.

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Figure captions

Figure 1: Jurisdiction covered within this scoping review

Tables

Table 1: Overview of countries with currently (Feb. 2021)[1] missing WHO FCTC Core Questionnaire 2020 data by signature and ratification.

Participant [2]	Signature	Ratification, Acceptance (A), Approval (AA), Formal confirmation (c), Accession (a), Succession (d)
Albania	2004	2006
Angola	2004	2007
Bahamas	2004	2009
Barbados	2004	2005
Bhutan	2003	2004
Botswana	2003	2005
Central African Republic	2004	2006
Chat		
Dominica	2004	2006
Equatorial Guinea		2005a
Eswatini	2004	2006
Ethiopia	2004	2014
Greece	2003	2006
Guinea	2004	2007
Israel	2003	2005
Kazakhstan	2004	2007
Kenya	2004	2004
Kyrgyzstan	2004	2006
Liberia	2004	2009
Maldives	2004	2004
Malta	2003	2003
Marshall Islands	2003	2004
Romania	2004	2006
Rwanda	2004	2005
Saint Kitts and Nevis	2004	2011
Saint Vincent and the Grenadines	2004	2010
San Marino	2003	2004
Slovenia	2003	2005
South Africa	2003	2005
Sri Lanka	2003	2003
Tajikistan		2013a
Timor-Leste	2004	2004
Uganda	2004	2007
Ukraine	2004	2006
United States of America	2004	
Uzbekistan		2012a
Yemen	2003	2007
Zambia		2008a

[1] https://fctc.who.int/who-fctc/reporting/parties-reporting-timeline; access: 14.06.2021

[2] Participants with full core questionnaire datasets not included.

Reporting procedure: Parties are required to report at intervals of two years and not later than six months before the next regular session of the Conference of the Parties. Countries that did not either sign or ratify the WHO FCTC are not obliged to report data and are not included.

Table 2: Overview of Policy instruments covered by country

Policy instruments covered, organized by WHO FCTC articles	Number of studies per policy instruments and country evaluated			
	India	USA	Other	Overall
Not covered by WHO FCTC				
General aspects	2	2	4	8
Gutkha and pan masala ban	6			6
Article 6 (Price and tax measures)				
Tax	1	5		7
Online cross-country Tax			1	1
Article 8 (Protection from exposure)				
Smoke-free places laws (free from residues of smokeless tobacco consumption)		3		3
Article 9 (Regulation of content)				
Ban (flavoured products)				3
Article 11 (Packaging and labelling)				
Health warnings	1	1	1	4
Packaging and labeling	1			1
Article 13 (Advertisement)				
Advertising&Sales		1		1
Marketing&Sales		1		1
Sales/Advertisement ban near educational institutions	4			4
Online cross-country advertisement			1	1
Display ban			1	1
Article 16 (Sale to and by minors)				
Provisions to change the point-of-sale environment		1		1
Sales to minors		1		1
Product availability in pharmacies		1		1
Snuff ban			1	1
Snus ban			1	1

Table 3: Study population covered per country

Study population per Country	General Population	Students	Retailers/Vendors	user/former user	Shops, retailer (facilities)	School districts	Gender reported in any of the studies
USA	x	x	x		X		x
India	x	x	x	x (gutkha)	X	X	x
Bangladesh	x						
Bhutan	x						
Myanmar		x					
South Africa							
Finland	x	x					x
Sweden	x						
Norway			x		X		

Table indicates study population covered, not frequency.

Table 4: Articles covered in Mehrotra et al. and the actual scoping review

WHO FCTC Article		Data at macro level (Mehrotra et al.) for countries covered by included studies	Data based on included national policy evaluation studies	Countries covered by included studies
PART II	**Objective, guiding principles and general obligations**			
3	Objective	x		
4	Guiding Principles			
5	General Obligations			
Part III	**Measures relating to the reduction of demand for tobacco**			
6	Price and tax measures to reduce the demand for tobacco	x (Bangladesh, India, Norway, South Africa)	x	India, USA, EU
7	Non-price measures to reduce the demand for tobacco			
8	Protection from exposure to tobacco smoke		x	USA
9	Regulation of the contents of tobacco products	x	x	USA
10	Regulation of tobacco product disclosures	x		
11	Packaging and labelling of tobacco products	x (Bangladesh, India, Myanmar, Norway, South Africa, Sweden)	x	India, USA, Bangladesh
12	Education, communication, training and public awareness	x		
13	Tobacco advertising, promotion and sponsorship	x (Bangladesh, Bhutan, Finland, India, Myanmar, Norway, South Africa, Sweden)	x	EU, India, USA
14	Demand reduction measures concerning tobacco dependence and cessation	x		
Part IV	**Measures relating to the reduction of the supply of tobacco**			

15	Illicit trade in tobacco products			
16	Sales to and by minor	x (Bhutan)	x	USA, India, Finland, Norway
17	Provision of support for economically viable alternative activities			
Part V	**Protection of the environment**			
18	Protection of the environment and the health of persons			
Part VI	**Questions related to liability**			
19	Liability			
PART VII	**Scientific and technical cooperation and communication of information**			
20	Research, surveillance and exchange of information	x		
21	Reporting and exchange of information			
22	Cooperation in the scientific, technical and legal fields and provision of related expertise			

1

Appendix 1: Example search query in PubMed and search terms, November 2019

Table A1: Keywords

Keyword	Search
Block A: Smokeless tobacco	
"smokeless tobacco" OR "nasal snuff" OR "moist snuff" OR "snus" OR "chewing tobacco" OR "SLT" OR "ST Product*" OR "Betel quid" OR "paan" OR "Gul" OR "pan masala" OR "gutkha" OR "Mishri" OR "oral tobacco" OR "dip tobacco"	Title/Abstract
Smokeless tobacco	MeshTerm
Block B: Public policy	
"public policy control" OR "public control policy" OR "control policy" OR "policy control" OR "regulation" OR "national strategies" OR "national action plan*" OR "public policy intervention" "enforcement" OR "implementation" OR "public policies" OR "policy making" OR "government regulation" OR "public regulation" OR "public policy" OR "formal social control"	Title/Abstract
Public policy	MeshTerm

Example search query in PubMed (November 2019)

((((((((((((((((((((((((("smokeless Tobacco"[Title/Abstract]) OR "nasal snuff"[Title/Abstract]) OR "moist snuff"[Title/Abstract]) OR snus[Title/Abstract]) OR "chewing tobacco"[Title/Abstract]) OR "SLT"[Title/Abstract]) OR "ST Product*"[Title/Abstract]) OR "Betel quid"[Title/Abstract]) OR "paan"[Title/Abstract]) OR Gul[Title/Abstract] OR "pan masala"[Title/Abstract]) OR "gutka"[Title/Abstract]) OR mishri[Title/Abstract]))))

OR smokeless tobacco[MeSH Terms] OR smokeless tobaccos [MeSH Terms]))))) OR smokeless tobacco cessation[MeSH Terms])) OR tobacco cessations, smokeless[MeSH Terms])) OR "oral tobacco"[Title/Abstract]) OR "dip tobacco"[Title/Abstract]))

AND ((((((((((((((government regulations[MeSH Terms]) OR (((((("public policy control"[Title/Abstract]) OR "public control policy"[Title/Abstract]))

OR (((((((("Public policy"[MeSH Terms]) OR "policy making"[MeSH Terms])) OR ((((("control policy"[Title/Abstract]) OR "policy control"[Title/Abstract])) OR regulation[Title/Abstract])))))) OR government regulation[MeSH Terms])

OR "National strategies"[Title/Abstract]) OR "National Action Plan*"[Title/Abstract]) OR "public policy intervention"[Title/Abstract])) OR harm reduction[MeSH Terms]) OR "supply reduction"[Title/Abstract]) OR "demand reduction"[Title/Abstract]) OR taxation[Title/Abstract]) OR "information campaign"[Title/Abstract]) OR "consumer behavior"[Title/Abstract]) OR "public policy"[Title/Abstract])

Appendix 2: Overview studies characteristics

Author	Country/ Jurisdiction	Region, if specified	Policy, if specified	Instrument evaluated	WHO FCTC article	Sample characteristics if specified				Study design	Results	Context/comments
						N (specification)	Specification	Age	Gender			
Schensul et al. 2013	India city	Low-income community of Mumbai	Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act (COTPA), 2003	COTPA general		55 (Shop owners)				Mixed method (spatial analyses and interviews)	Consumption accepted also for minors, easy to reach, sales also to minors, form of income	Barriers: Lack of comprehensive information and awareness of the act, missing economic alternatives, cultural acceptance of tobacco use, lack of political support and tobacco control of lower priority
Sharma et al. 2010	India city	Guwahati Municipal Corporation in Assam		COTPA general		300		Mean age 41 years	52% males	Cross-sectional study	Older than 50 years, more than 10 years of schooling—likely to have good awareness, middle SES and perception of second-hand smoking as harmful; more than 10 years of schooling → positive attitudes towards COTPA	Role of education
Aruna et al. 2010	India city	Muradnagar, Uttar Pradesh		Health warnings	11	(Retail sales outlets)				Snowball/network sampling design	Mostly followed, not for gutkha	Locally marketed products not compliant
Athuluru et al. 2018	India city	Nellore city		Sales/ Advertisement ban near educational institutions	16, 13	400 (Institutional personnel (students, teaching staff, nonteaching staff and workers)		18–60 18–22 years (253; 63.2%) 25–60 years (147; 36.8%)	Males 285 (71.3%), females 115 (28.7%).	Cross-sectional study	75% and more not aware of the prohibition	Income distribution
Balappanavar et al. 2017	India city	Central Delhi		Sales/ Advertisement ban near	16, 13	15 (School districts)				Cross-sectional study	Not followed/no compliance	Delhi as capital not representative

				educational institutions						
Mistry et al. 2015	India city	Mumbai		Sales/ Advertisement ban near educational institutions	16,13	1533 (Students)	8th to 10th grade (14–16)		Survey	Correlation between density and SLT use	Enforcement needed, complete ban of all advertisement
Pimple et al. 2014	India city	Mumbai		Sales/ Advertisement ban near educational institutions	16, 13	222 (Tobacco retail outlets)			Cross-sectional study	Most vendors know about it, only a few comply	Problem of mobile tobacco sellers
Panigrahi 2018	India city	Slum areas of Bhubaneswar, the capital city of Odisha state		Packaging and labelling	11	134 (Retail outlets)			Cross-sectional study	Mixed compliance	Worse compared to cigarette brands
Kumar 2018	India city	Mumbai & Indore		Gutkha ban		20 (Gutkha vendors)			Qualitative study (KAP survey)	Ban known	Shift to other SLT products, Gutkha still available at high prices, switching to other tobacco products
Mishra 2014	India city	Mumbai, Maharashtra		Gutkha and pan masala ban		68 users (Gutkha); 5 vendors (Users, vendors)	19–60		Cross-sectional study	Quitting or reduction in consumption; vendors stopped selling because of fear of law enforcement	Still available on the black market
Nair 2012	India city	Mumbai		Gutkha and pan masala ban		347 shops; 13 interviews with shop owners; 9 interviews with users (Shop owners, users)			Mixed method	Sales shift to other tobacco products; not eliminating local gutkha supply, demand and use	Black market
Reddy et al. 2016	India district	Rangareddy District		Gutkha ban		384 vendors; 368 users (Shop owners, users)			Cross-sectional study	49.2% of users aware of the ban	29.8% Gutkha users switched to other tobacco products after the ban; newspapers main source of information regarding the ban (45.8%) (high literacy of study participants); illicit trade
Dhumal et al. 2013	India state	Maharashtra	Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011	Gutkha and pan masala ban		11 (Ex-gutkha users)		Male	Focus group discussion	2 users stopped the consumption of gutkha or any other tobacco product whereas 8 users switched to other tobacco products	Gutkha still available to regular customers but at higher price

John et al. 2019	India national	Goods and Services Tax (GST), 2017	Tax	6			Pre-post study design	Changes in Percentages Price: 6.07% increased Consumption: -6.01% (Reduced) Revenue: 4.66% increased
Farley et al. 2017	USA city	New York City	Ban (flavoured products)	10		13–17	Pre-post study design, interrupted time-series analysis	decline in flavoured sales before enforcement of the NYC flavoured tobacco product sales ban took effect, as tobacco retailers were notified a few months before enforcement would commence
Kephart et al. 2019	USA city	Boston	Ban (flavoured products)	10			Pre-post study design	Stores selling flavoured tobacco products at baseline = (353/353)100% Stores selling flavoured tobacco products at follow-up = 14.4% Average number of flavoured tobacco products sold at baseline = 19.5 products and at follow-up = 0.39 Stores with flavoured tobacco products advertisement at baseline = 58.9% and at follow-up = 28% SLT/Dissolvable flavoured products brands sold at the baseline = 247 (3.6%) brands out of 6916 total tobacco brands Follow-up: 0 SLT flavoured brands sold
Rose et al. 2018	USA city	North Carolina (3 cities)	Provisions to change the point-of-sale environment	16	324 (Retailers)		RTC	15.1% violated the law in at least 1 point-of-sale provision

Rogers et al. 2018	USA city, county	New York City, 10 non-NYC counties in the NY DMA (no policy restriction): Nassau, Rockland, Suffolk, Westchester Bergen, Essex, Hudson, Middlesex, Monmouth and Union	Ban (flavoured products)	10	(Retail scanner data)			Quasi-experimental comparison design	Flavoured SLT sales declined to near zero in NY compared to other US districts	strict enforcement
Frick et al. 2012	USA state	Ohio	Sales & Advertising	16, 16	(Retailers)			Cross-sectional study	POS advertising and use of predominant tobacco signage and displays have been found to be more prevalent in stores where youth are more likely to visit	
Ohsfeld et al. 1997	USA state		Tax and Smoking in public places	6, 8	Representative sample of over 100,000 individuals (National US population)		Male	Secondary data analyses	Higher cigarette taxes associated with higher SLT use Smoking ban in public places no effect on ST	
Klein et al. 2012	USA state	Ohio	Marketing & Sales	16	86 baseline; 79 follow-up (Tobacco licensed retail outlets)			Trend analysis	Significant reduction in the frequency of exterior and interior advertisements	Neighbourhood; number of brands advertised doubled
Choi et al. 2014	USA state	Minnesota	Sales to minors	16	71 (Retailers)			Survey	4 (12.9%) of the sampled tobacco retailers sold snus to the underage buyer	
Ciecierski et al. 2011	USA state		Various national control policies		58,640 (College students)	18–25		Secondary data analyses	Higher state expenditures on tobacco control programs are associated with reductions in the prevalence of smokeless tobacco and cigar use among college students	
Goel et al. 2005	USA state		Tax	6		Whole population		Cross-sectional study	Percentage increase in cigarette taxes has greater potential to decrease smoking prevalence than a similar increase in smokeless taxes has on ST prevalence; Restricting minors' access to tobacco increases their	Spill-over effects between smoking and SLT policies (interdependencies)

										smokeless consumption, especially girls	
Hawkins et al. 2018	USA state			Tax	6	499,381	14–18 Adolescent	50.1% female	Cross-sectional study	No evidence for an effect of chewing tobacco taxes on adolescent smokeless tobacco use	Increase in cigarette taxes → increase in SLT use by males
McClelland 2015	USA state	Mississippi		Tax and Smoke-free laws	6, 8	(Public school students)	9th, 10th, 11th and 12th grade		Trend analysis	No effect	
Mumford et al. 2005	USA state			Tax and Smoke-free laws	6, 8	41,000–64,000 individuals representing 29,000–50,000 households	≥25	Male	Secondary data analyses	Current smoker: home smoking ban→ more likely to report concurrent SLT use; work ban associated with reduced odds of concurrent SLT use Excise taxes, on either cigarettes or SLT products unrelated to odds of current use	tax rates did not appear to make a difference in behavior, suggesting that SLT and cigarettes may be complements for at least some concurrent users.
Seidenberg et al. 2013	USA state	Massachusetts		Product availability in pharmacies	16	Licensed pharmacies			Cross-sectional study	69% had a license to sell tobacco products (all cigarettes, moist snuff (53%), snus (14%)	Made up 9% of licensed tobacco retailers
Huang 2012	USA national		Children's Health Insurance Program Reauthorization Act (CHIPRA), 2009	Tax	6		14–18		Pre-post study design, interrupted time-series analysis	Decrease in prevalence after 1 month by 0.8–1.2% points	
Chaloupka et al. 1997	USA national		Policy not specified	Several tobacco control policies		19,581 (Students)	School grades 8, 10 and 12 (13–18)	Male	Secondary data analyses	Increase in ST tax would reduce probability of ST use in males, but not in ST male users	Tobacco control policy mix (higher smoke- less tobacco taxes, higher minimum legal purchase ages for tobacco products, strong tobacco licensing provisions, restrictions on the distribution of free samples of tobacco products, the posting of minimum purchase age signs) is effective in reducing adolescent male smokeless tobacco use

Agaku et al. 2016	USA national	Comprehensive Smokeless Tobacco Health Education Act of 1986 & Amendment in 2009 by the Family Smoking Prevention and Tobacco Control Act	Health warnings	11	1,626		≥18	Secondary data analyses	Perception increased with differences in income, education, gender, age and new SLT products	Differences between income groups and education level (higher income=higher awareness)
Ayo-Yusuf 2005	South Africa national	Tobacco Products Control (TPC) Act of 1993 (Act 83 from 1993)	General				≥ 16	Secondary data analyses	Snuff decreased; despite the lack of excise tax	High rates in black African women; previously used only by elders, remains high among adolescents
Gurung et al. 2016	Bhutan national	Tobacco Control Act, 2010	General				18–69	Cross-sectional study	¼ of all adults use any kind of tobacco, majority SLT	
Huhtala et al. 2006	Finland national	Tobacco Control Act Amendment (TCAA), 1995	Snus ban	16	n = 73,946; 3,105-8,390 per year	Students	12–, 14–, 16–, 18	Secondary data analyses	No change in snus use	Increased amounts of snus ownership for "personal use" because "personal use" is allowed
Latt et al. 2018	Myanmar national	Control of Smoking and Consumption of Tobacco Product Law (Tobacco Control Law)	General			High school students		Cross-sectional study	Awareness high	but still sold, no awareness that noncompliance could be punished with fine
Merne et al. 1998	Finland national	Tobacco Control Act Amendment (TCAA), 1995	Snuff ban	16		High school students	15–23	Cross-sectional study	Snuff use declined from 9%→8% with highest rates in suburban schools	
Patja et al. 2009	Finland national	Tobacco Control Act Amendment (TCAA), 1995	General		12,837 men and 12,994 women from Sweden. 9,510 men and 10,859 women from Finland		18–64 Male & female	Secondary data analyses	Sweden increased, Finland low	Highest prevalence of daily use in women (5% in the age group of 20–40)
Patja et al. 2009	Sweden national	Swedish Tobacco Control Act (TCA), 1993	General							
Peeters et al. 2013	EU Supra-national	Directive 2008/118/EC & Directive 2003/33/EC (tobacco advertising across) EU states	Online cross-country tax and advertisement	6, 13				Case study	Tax was added, but cross-country selling mostly possible	

Rahmen et al. 2019	Bangladesh	Regulation of images through Section 10(1) Smoking and Tobacco Products Usage (Control) (Amendment) Act, 2013; this aligns with Bangladesh obligations under FCTC (ratified in 2004)	Health warnings	11		Whole population	Pre-post study design, interrupted time-series analysis	SLT products non-compliant
Scheffels et al. 2013	Norway	Tobacco Control Act, 1973	Display ban	16	(Shops, users)	15–54	Quantitative descriptive study	Compliance was 98% for snus

Pimple et al. 2014, Ohsfeldt et al. 1997, McClelland et al. 2015 and Mumford et al. 2005 report on two instruments; Patja et al 2009 report on two countries: Finland and Sweden.

Appendix 3: Overview of the policies evaluated in the articles included in the scoping review

Country	Policy name	Summary
India	Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act (COTPA), 2003	The Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act, 2003 (Act No. 34 of 2003) (COTPA) is the principal law governing tobacco control in India. COTPA is comprehensive, covering topics including, but not limited to: definitions of key terms; restrictions on smoking in public places; advertising, promotion and sponsorship; sales to minors; packaging and labelling; and enforcement and penalties. The Act does not apply to tobacco products which are to be exported. The law available here is in English only. The first provisions of COTPA entered into force on May 1, 2004. These provisions included Sections 1-5, 6(a), 12(1)(b), 12(2), 13(1)(b), 13(2), 14, 16, 19, 21-31. Sections 7(1)-(4), 8, 9, 10, and 20 took effect on December 1, 2007. Sections 12(1)(a), 13(1)(a), 15, 17, 18, 32, and 33 took effect on July 30, 2009. The Central Government issued rules pursuant to authority conferred under COTPA Section 6(b) regarding the sale of cigarettes around educational institutions, taking effect on September 18, 2009. The government has yet to notify two sections - Sections 7(5) (mandatory display of nicotine and tar contents) and 11 (regulation of tar and nicotine content). https://www.tobaccocontrollaws.org/
	Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011	The Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011 prohibit, among other things, tobacco and nicotine from being used in any food products. Courts in several states have relied on this provision to impose bans on the manufacture, distribution and sale of "gutkha" or "pan masala." https://www.tobaccocontrollaws.org/
	Goods and Services Tax (GST), 2017	Article 366(12A) Definition of GST: “Goods and services tax” means any tax on supply of goods, or services or both except taxes on the supply of the alcoholic liquor for human consumption Tobacco: Part of GST but power to levy additional excise duty with Central Government http://www.gstcouncil.gov.in

USA	Comprehensive Smokeless Tobacco Health Education Act of 1986	This Act, as amended by the 2009 Family Smoking Prevention and Tobacco Control Act, requires manufacturers, packagers and importers of smokeless tobacco products to place one of four statutorily prescribed, health-related warning labels on product packages and in advertisements, on a rotational basis, as reviewed and approved by the Secretary of the Department of Health and Human Services. The Act prohibits any advertising of smokeless tobacco products on radio, television or other media regulated by the Federal Communications Commission. https://www.ftc.gov/enforcement/statutes/comprehensive-smokeless-tobacco-health-education-act-1986
	Amendment in 2009 by the Family Smoking Prevention and Tobacco Control Act	Prohibited the manufacturing, marketing and sale of cigarettes containing "characterizing flavors," such as vanilla, chocolate, cherry, and coffee. This prohibition extends to flavoured cigarettes and flavoured cigarette "component parts," such as their tobacco, filter or paper. However, the prohibition exempts the flavours of menthol and tobacco and does not apply to non-cigarette tobacco products, such as electronic cigarettes, cigars, smokeless tobacco, hookah tobacco and their flavoured component parts. https://www.publichealthlawcenter.org/sites/default/files/resources/tclc-fs-global-flavored-regs-2015.pdf
	Children's Health Insurance Program Reauthorization Act (CHIPRA), 2009	CHIPRA increased federal excise tax rates on tobacco products, effective April 1, 2009, to fund the Children's Health Insurance Program (CHIP) https://www.everycrsreport.com/reports/R40130.html
South Africa	Tobacco Products Control (TPC) Act of 1993 (Act 83 of 1993)	Tobacco Products Control Act 83 of 1993 is the primary tobacco control law in South Africa and governs many aspects of tobacco control, including, but not limited to, public smoking restrictions; packaging and labeling of tobacco products; and tobacco advertising, promotion and sponsorship. Several tobacco control regulations have been issued under this law including: 1) Regulations Relating to the Labeling, Advertising, and Sale of Tobacco Products (which regulate packaging and labeling); 2) Notice Relating to Smoking of Tobacco Products in Public Places (which regulates public smoking); 3) Regulations Relating to the Point of Sale of Tobacco Products (which regulate signs at point of sale and product display); and 4) Regulations Relating to Provisions for Exemption For Unintended Consequences and the Phasing out of Existing Sponsorship or Contractual Obligations (which exempt cross-border advertising from the ban on advertising, promotion and

		sponsorship). It was amended by General Law Fifth Amendment Act 157 of 1993, Tobacco Produc ts Control Amendment Act 12 of 1999, Tobacco Products Control Amendment Act 23 of 2007 and Tobacco Products Control Amendment Act 63 of 2008, the primary tobacco control law of South Africa. It governs, among other things, smoking restrictions; tobacco advertising, promotion and sponsorship; and packaging and labeling. https://www.tobaccocontrollaws.org/legislation/country/south-africa/laws
Bhutan	Tobacco Control Act, 2010	The Tobacco Control Act of Bhutan 2010 is the primary piece of tobacco control legislation. The law prohibits the cultivation, manufacture, sale, and distribution of tobacco products within Bhutan, a policy dating back to 2004. Instead, a limited quantity of tobacco products may be imported for personal consumption only. In addition, the law governs smoke-free places; tobacco advertising, promotion and sponsorship; and requires that imported products bear the health warnings required in the country of origin. The Tobacco Control Amendment Act of Bhutan 2012 amends the primary law. The Tobacco Control Rules and Regulations 2013 were issued under the Tobacco Control Act and govern smoke-free places; importation and duties; and duties and powers of enforcement authorities. In addition, Public Notification No. 7345 provides additional information related to the ban on smoking in public places and the duties placed on persons in charge of the premises. https://www.tobaccocontrollaws.org/legislation/country/bhutan/summary
Myanmar	Control of Smoking and Consumption of Tobacco Product Law (Tobacco Control Law; TCL), 2006	The Control of Smoking and Consumption of Tobacco Product Law was enacted in 2006, repealing the Law of the Prohibition of Smoking at the Entertainment Building Act, 1959. Two notifications have been issued by the Ministry of Health specifying requirements of smoke-free places. The notifications are: (1) Ministry of Health Notification No. 5/2014, Order Stipulating the Caption, Sign and Marks Referring to the “No-Smoking Area”; and (2) Ministry of Health Notification No. 6/2014, Order Stipulating the Requirements to be Managed at the Specific Area where Smoking is Allowed. In addition, the President’s Office issued a letter with instructions on tobacco use in government offices. Ministry of Health Proclamation No. 11/2016, Order of Printing Warning Messages and Texts on the Packaging of Tobacco Products prescribes the requirements of the graphic health warnings that must appear on product packaging. https://www.tobaccocontrollaws.org/legislation/country/myanmar/summary
Finland	Tobacco Control Act Amendment (TCAA), 1995	The national Tobacco Control Act (TCA) of 1976 and its amendment of 1995 (Tobacco Control Act Amendment, TCAA) form the main basis of the measures applied. The TCA banned tobacco advertising, outlawed smoking in most public places, including public transport, prohibited tobacco sales to persons under 16 years of age and introduced mandatory health warnings on packages.

		Section 51 Prohibition on the sale of smokeless tobacco products Smokeless tobacco products may not be sold or otherwise supplied or passed on. (Total snus and snuff ban) Finnish Act on measures to reduce tobacco smoking: English version of the 1976 TCA and the 1995 TCAA at http://www.finlex.fi/en/laki/kaannokset/1976/en19760693.pdf; Leppo K, Vertio H.Smoking control in Finland: a case study in policy formulation and implementation , Health Promot, 1986, vol. 1 (pg. 5-16) Puska P KorhonenHJ, Uutel A, et al. PuskaP, ElovainioL, VertioH. Anti-smoking policy in Finland , Smokefree Europe: A Forum for Networks, 1997
Swedish	Swedish Tobacco Control Act (TCA), 1993	The Tobacco Control Act of 1993 is the primary piece of tobacco control legislation in Sweden. Several acts have been passed amending the 1993 law. Among them, SFS 2010:682 amends supervisory and enforcement provisions; SFS 2010:727 amends advertising provisions; and SFS 2010:1317 amends product control provisions. The Tobacco Control Act was most recently amended by SFS 2016:353. SFS 2016-354, the Tobacco Regulation, contains complementary provisions to the Tobacco Control Act and grants authority to the public health authority to issue regulations under specific articles of the Tobacco Control Act. One set of such regulations is HSLF-FS 2016:46 (as amended by HSLF-FS 2016:77), which sets forth specific requirements for pictorial health warnings and other labeling requirements. Other laws impact tobacco advertising, promotion and sponsorship in addition to the Tobacco Control Act. Specifically, the Radio and Television Act prohibits tobacco sponsorship of radio and television programs and paid placement of tobacco products on TV programs. The Marketing Act provides penalties for violations of advertising, promotion and sponsorship provisions of the Tobacco Control Act. The Freedom of Press Act specifically states that it does not apply to commercial advertising for tobacco products. https://www.tobaccocontrollaws.org/legislation/country/sweden/summary
EU	Directive	Directive 2008/118/EC lays down general arrangements in relation to excise duty which is levied directly or indirectly on the

	2008/118/EC & Directive 2003/33/EC (tobacco advertising across EU countries)	consumption of the following goods (hereinafter 'excise goods'): (c) manufactured tobacco covered by Directives 95/59/EC, 92/79/EEC and 92/80/EEC. Directive 2003/33/EC of the European Parliament and of the Council of 26 May 2003 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products https://eur-lex.europa.eu/homepage.html
Bangladesh	Regulation of images through Section 10(1) Smoking and Tobacco Products Usage (Control) (Amendment) Act 2013, this aligns with Bangladesh obligations under FCTC (ratified in 2004)	The Smoking and Using of Tobacco Products (Control) (Amendment) Act, 2013 contains amendments to the 2005 Act of the same name. The amended act is the principal law governing tobacco control in Bangladesh. The law is comprehensive and provides for: restrictions on smoking in public places; restrictions on tobacco advertising, promotion and sponsorship; graphic health warnings on packaging and labeling; and loans for the cultivation of other cash crops as alternatives to tobacco, among others. https://www.tobaccocontrollaws.org/legislation/country/bangladesh/laws
Norway	Tobacco Control Act, 1973	Act No. 14 of March 9, 1973 relating to the Prevention of the Harmful Effects of Tobacco (the Tobacco Control Act) is the primary tobacco control law in Norway. The law governs, among other things, smoking restrictions, tobacco advertising and tobacco packaging and labeling. The law has been amended many times. A ban on all forms of tobacco advertising (including indirect advertising) was implemented in Norway in 1975. Regulations concerning packaging include health warnings (introduced in 1975), rules about declarations of product content on packages (1984) and restrictions on the use of innovative packaging to attract consumers' attention. On January 1, 2010, Norway removed point-of-sale displays of tobacco products through further provisions of the Norwegian Tobacco Act from

	1973. The legislation mandated that tobacco products and related equipment (paper for rolling tobacco, etc.) must be stored out of view from consumers. The ban applies also to imitations of tobacco products as well as vending machine cards that give customers access to takeout tobacco products and related equipment.
	Scheffels, Janne; Lavik, Randi, Out of sight, out of mind? Removal of point-of-sale tobacco displays in Norway Tobacco Control, May 2013;22(e1):e37-e42 2013 May

All webpages accessed: 20.04.2020.

Appendix 4: Overview about public policies and instruments within the countries

Table Appendix 4: Overview about public policies and policy instruments evaluated within the countries

Country, number of studies, Classifications by income level: 2019–2020 (World Bank)	Public policy	Policy instrument	Corresponding FCTC article	Author
USA N=17, High-income	Comprehensive Smokeless Tobacco Health Education Act of 1986 & Amendment in 2009 by the Family Smoking Prevention and Tobacco Control Act	Health warning	11	Agaku et al. 2016
		Ban (flavoured products)	9	Farley et al. 2017, Kephart et al. 2019, Rogers et al. 2018
		Sales & Advertising	16, 13	Frick et al. 2012
		Tax	6	Ohsfeld et al. 1997
		Smoke-free places*	8	Ohsfeld et al. 1997
		Sales & Marketing	16, 13	Klein et al. 2012
		Provisions to change the point-of-sale environment	16	Rose et al. 2018
	Children's Health Insurance Program Reauthorization Act (CHIPRA), 2009	Tax	6	Huang et al. 2012
	Policies not further specified	Several tobacco control policies		Chaloupka et al.1997, Ciecierski et al. 2011
		Sales to minors	16	Choi et al. 2014
		Tax	6	Goel et al. 2005, Hawkins et al. 2018, McClelland et al. 2015, Mumford et al. 2005
		Smoke-free places*	8	McClelland et al. 2015, Mumford et al. 2005
		Product availability in pharmacies	16	Seidenberg et al. 2013
India n=14, Low-middle-income	Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act (COTPA), 2003	COTPA general		Schensul et al. 2013, Sharma et al. 2010
		Health warnings	11	Aruna et al. 2010
		Sales/Advertisement ban near educational institutions	16, 13	Athuluru et al. 2018, Balappanavar et al. 2017, Mistry et al. 2015, Pimple et al. 2014

		Packaging and labelling	11	Panigrahi et al. 2018
	Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011	Gutkha and pan masala ban		Dhumal et al. 2013, Kumar et al. 2018, Mishra et al. 2014, Nair et al. 2012, Pimple et al. 2014, Reddy et al. 2016
	Goods and Services Tax (GST), 2017	Tax	6	John et al. 2019
Bangladesh N=1, Lower-middle-income	Regulation of images through Section 10(1) Smoking and Tobacco Products Usage (Control) (Amendment) Act, 2013; this aligns with Bangladesh obligations under FCTC (ratified in 2004)	Health warnings	11	Rahmen et al. 2019
Bhutan N=1, Lower-middle-income	Tobacco Control Act, 2010	General		Gurung et al. 2016
Myanmar N=1, Lower-middle-income	Control of Smoking and Consumption of Tobacco Product Law (Tobacco Control Law; TCL), 2006	General		Latt et al. 2018
South Africa N=1, Upper-middle-income	Tobacco Products Control (TPC) Act of 1993 (Act 83 from 1993)	General		Ayo-Yusuf 2005
Finland N=3, High-income	Tobacco Control Act Amendment (TCAA) 1995	Snuff ban	16	Merne et al. 1998
		Snus ban	16	Huhtala et al. 2006
		General		Patja et al. 2009
Sweden N=1, High-income	Swedish Tobacco Control Act (TCA), 1993	General		Patja et al. 2009
Norway N=1, High-income	Tobacco Control Act, 1973	Display ban	13	Scheffels et al. 2013
EU N=1, n/a	EU Tobacco Products Directive (TPD), Directive 2008/118/EC, Directive 2003/33/EC	Online cross-country tax and advertisement	6,13	Peeters et al. 2012

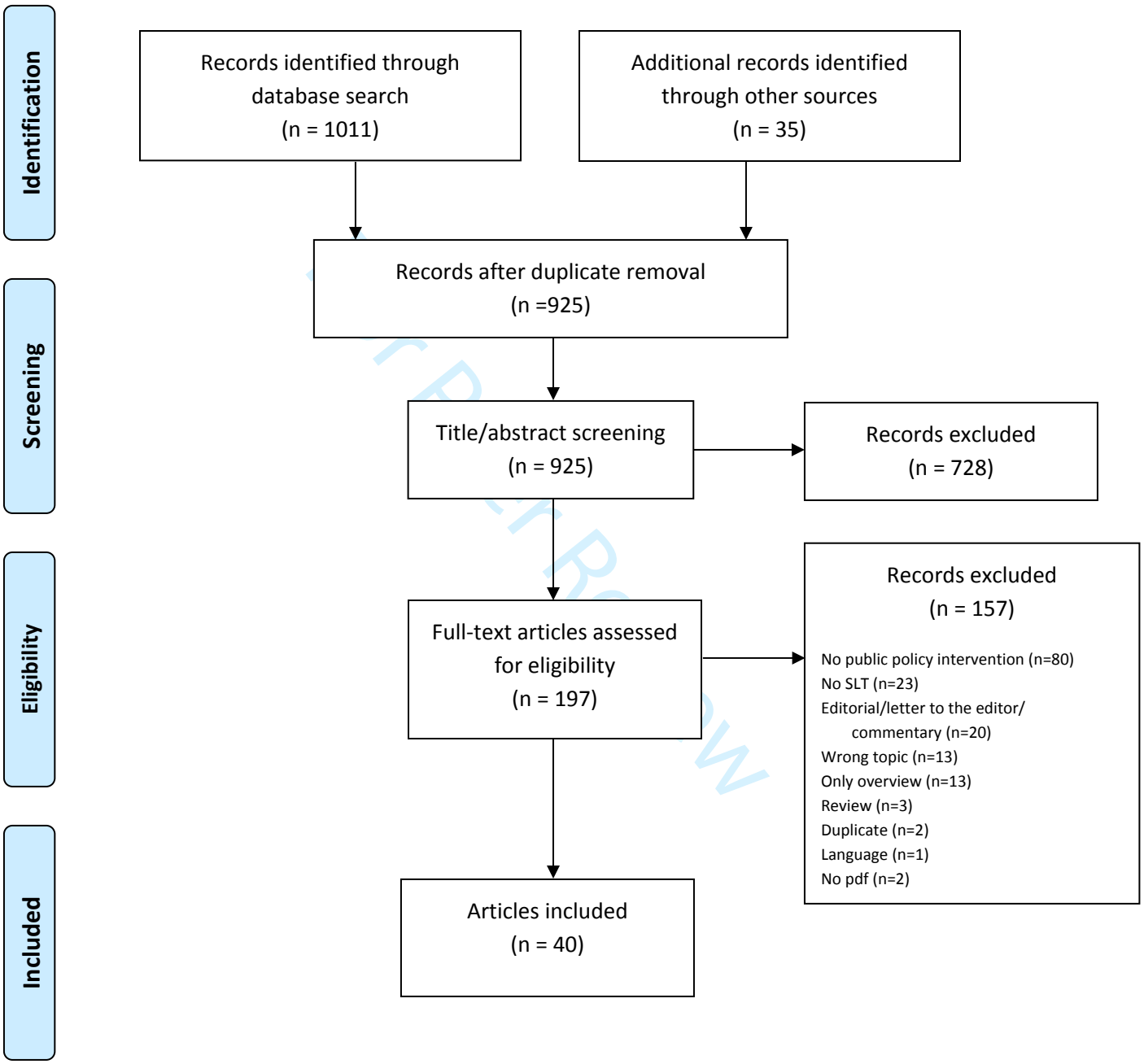
* Studies analysing smoke-free places evaluated the litter, which indicated the consumption of smokeless tobacco.

Appendix 5: WHO Framework Convention on Tobacco Control (WHO FCTC)

	Articles		Topic	Content (short)
Part I	1-2	Introduction		
Part II	3-5	establish the objective, guiding principles and general obligations engendered by the treaty	Lobbing/industry interference (Art. 5.3)	Call for a limitation in the interactions between lawmakers and the tobacco industry.
Part III	**Demand-side reduction measures**			
	6	Price and tax measures to reduce the demand for tobacco	Demand reduction	Tax measures to reduce tobacco demand.
	7	Non-price measures to reduce the demand for tobacco	Demand reduction	Other measures to reduce tobacco demand.
	8	Protection from exposure to tobacco smoke	Passive Smoking	Obligation to protect all people from exposure to tobacco smoke in indoor workplaces, public transport and indoor public places
	9	Regulation of the contents of tobacco products	Package and labeling	Large health warning (at least 30% of the packet cover, 50% or more recommended), plain packaging is recommended; deceptive labels ("mild", "light", etc.) are prohibited.
	10	Regulation of tobacco product disclosures	Regulation	The contents and emissions of tobacco products are to be regulated and ingredients are to be disclosed
	11	Packaging and labelling of tobacco products	Package and labeling	Large health warning (at least 30% of the packet cover, 50% or more recommended), plain packaging is recommended; deceptive labels ("mild", "light", etc.) are prohibited.
	12	Education, communication, training and public awareness	Awareness	Public awareness for the consequences of smoking.
	13	Tobacco advertising, promotion and sponsorship	Advertising	Comprehensive ban, unless the national constitution forbids it.
	14	Demand reduction measures concerning tobacco dependence and cessation	Addiction	Addiction and cessation programs.
Part IV	**Supply-side reduction measures**			
	15	Illicit trade in tobacco products	Illicit trade	Action is required to eliminate illicit trade of tobacco products.
	16	Sales to and by minors	Minors	Restricted sales to minors.
	17	Provision of support for economically viable alternative activities		

Part V	**Protection of the environment**			
	18	Protection of the environment and the health of persons	Environment	Protection of environment and the health of persons in respect to tobacco cultivation and manufacture
Part VI	**Questions related to liability**			
	19	Liability	Regulation	Taking legislative action or promoting their existing laws, where necessary, to deal with criminal and civil liability
Part VII	**Scientific and technical cooperation and communication of information**			
	20	Research, surveillance and exchange of information	Research	Tobacco-related research and information sharing among the parties.
	21	Reporting and exchange of information	Research	Tobacco-related research and information sharing among the parties.
	22	Cooperation in the scientific, technical and legal fields and provision of related expertise	Research	Tobacco-related research and information sharing among the parties.
Part VIII	**Institutional arrangements and financial resources**			
	23-26			
Part IX-X				
	27	Settlement of disputes		
	28-29	Development of the convention		
Part XI	**Final provision**			
	30-38	Covering statutory matters such as means of acceding to the Convention, entry into force		

Appendix 2.1: Flow diagram



Scoping review of existing evaluations of smokeless tobacco control policies: What is known about countries covered, level of jurisdictions, target groups studied and instruments evaluated?

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Abstract

Objective – The implementation of smokeless tobacco control policies lags behind those for smoking. This scoping review summarises the studies that evaluated public policies on smokeless tobacco regulation (SLT) and provides an overview of the jurisdictional level, target groups and policy instruments.

Methods – Seven databases were systematically searched for studies reporting on public policies regulating SLT. All studies were independently screened by two reviewers. Data extraction was performed using a predefined extraction form. Extraction was replicated for 10% of the identified studies for quality assurance. A narrative synthesis of the included studies was used to analyse and interpret the data. The protocol was published beforehand with the OSF.

Results – 40 articles comprising 41 studies were included. Most of the studies reported in the articles were conducted in the USA (n=17) or India (n=14). Most studies reported outcomes for students (n=8), retailers/sellers (n=8) and users/former users (n=5). The impact of public policies on smokeless tobacco use in general was most frequently assessed (n=9), followed by the impact of taxes (n=7), product bans (n=6), sales/advertising bans near educational institutions (n=4) and health warnings (n=3) on consumer behaviour.

Conclusions – There are major gaps in the evaluation of smokeless tobacco regulation studies that need to be filled by further research to understand the observed outcomes. WHO reporting on FCTC implementation should be linked to studies evaluating smokeless tobacco control measures

at all levels of jurisdictions and in countries that are not members of the WHO FCTC or do not provide data.

Keywords: Smokeless tobacco, tobacco control policy, national control policy, policy evaluation, WHO FCTC, policy implementation

Implication

Large gaps in the evaluation of SLT control policies exists. For some countries, WHO FCTC evaluations are available for different levels of jurisdictions. In countries with a strong federal structure, there is a lack of data that goes beyond the national level to provide a more detailed look at compliance, indirect effects or implementation gaps. More research is needed at all levels of jurisdictions, that add to the work of the WHO to understand what works for which target group, how the different levels of jurisdiction interact, how the real-world context can be incorporated, and what indirect effects may occur.

INTRODUCTION

Smokeless tobacco (SLT) is used by more than 300 million people worldwide[1, 2]. The geographical distribution of SLT use varies widely. While most SLT users (82 %) live in South and South-East

Asia, SLT is also widespread in Central Asia, the Scandinavian countries, North America and many African countries (e.g. Nigeria, Ghana, Algeria, Cameroon, Chad, Senegal, Sudan and South Africa)[3, 4]. SLT use is a risk factor for cancers of the head and neck[5] and is associated, for example, with cardiovascular disease and adverse reproductive outcomes such as low birth weight, preterm and stillbirths[4, 6]. According to the Global Burden of Disease study, there were 55,600 deaths (95% UI 43,100-68,800) due to SLT in 2019, of which 46,000 (35,500-58,000) were in South Asia[7].

The WHO Framework Convention on Tobacco Control (FCTC) was adopted by the World Health Assembly in 2003 and was open for signature between June 2003 to June 2004, during which time 168 countries signed the treaty[8]. It provides a comprehensive strategy to combat the tobacco epidemic, including SLT (Appendix 5)[9]. The FCTC is WHO's first global public health treaty[10]. It is legally the international community's most powerful tobacco control instrument[11]. The Convention is binding on countries through ratification, acceptance, approval, formal confirmation or accession[12]. The WHO FCTC must be transposed into national law, applied and enforced to become part of the national law of a sovereign state. This includes comparing existing legislation with the treaty provisions, examining administrative structures and adapting them where necessary, and developing administrative and technical guidance for its application[13]. Currently, 182 Parties, whose populations represent 90% of the world's population, have signed the Convention[14]. Existing reviews of the impact of the FCTC indicate promising approaches to reducing tobacco use[9, 15]. Although SLT products fall within the policy framework of the WHO FCTC, they have not received the same priority as tobacco among FCTC Parties. Only 34 out of 180 Parties (as of 2019) tax or report taxing SLT products, six Parties measure SLT product content and constituents, and 41 of the Parties require pictorial health warnings on products. Only a few Parties collect or present data on smokeless tobacco use through global or national surveillance mechanisms (e.g. Global

Tobacco Surveillance System and WHO STEPwise) or have comprehensive bans on advertising, promotion or sponsorship of SLT[4].

The WHO FCTC has been the subject of several studies, both for smoking and SLT, e.g. by Chung-Hall et al., Mehrotra et al., Siddiqi et al. and Gravely et al.[4, 9, 16, 17]. These papers provide deep insights into the implementation of the WHO FCTC. They describe whether FCTC measures have been implemented at national level for SLT. However, they do not provide information on whether these measures have been evaluated. Furthermore, not all UN states have signed the Convention. Some Parties have signed the treaty but have not implemented it, e.g. the USA, Argentina, Cuba or Switzerland. Some Parties have not signed but ratified the Convention, e.g. Tajikistan, Bahrain and Zimbabwe. Other Parties have signed and ratified the Convention but do not report data to WHO on the status of their SLT responses (Table 1). For these countries, policy evaluation studies are one way to get an overview of the effectiveness of tobacco control policies. They summarise what data are available for which level of jurisdiction (state, county, city). This increases the explanatory power for the different policy instruments used depending on the underlying organisational structures and legal responsibilities. It provides an overview of tobacco control policy, which areas are covered, how target groups respond, what indirect effects (may) occur and what data gaps exist. Moreover, combining WHO reporting with data from sub-national levels (states, county, city) for countries reporting under the WHO system allows for a more detailed and nuanced understanding of compliance with the WHO FCTC Framework Convention in these countries.

This work adds to the existing literature. The aim of the scoping review is to summarise studies that have analysed government policies to control SLT use in order to fill the gaps in the WHO FCTC reporting system. The objectives are to identify: (1) countries for which studies evaluating public policies are available to complement existing WHO FCTC data, and (2) the level of

jurisdiction, population groups and instruments studied, and the impact on consumption behaviour reported in these studies.

METHODS

The scoping review follows a similar approach to a systematic review[18-21]. The Preferred Reporting Items for Systematic Reviews and Meta-Analysis: extension for Scoping Reviews (PRISMA-SCR and flow chart) were used to illustrate the flow of information through the different stages of the scoping review[22]. A study protocol was published in advance[23].

Search strategy and information sources

An information specialist advised on the search strategy. The search structure combined two concepts: SLT and public policy (Table 1, Appendix 1). Appropriate keywords, their synonyms and controlled vocabulary for relevant terms were used. The search syntax and vocabulary were adapted for subsequent searches in other databases on other platforms. The search strategy for Medline is available as a supplementary file (Appendix 1).

In November 2019, structured searches were conducted in the following electronic databases: Medline, PsychInfo, Science Citation Index, CINAHL, Econ.Lit, ASSIA and International Bibliography of the Social Sciences (IBSS). The reference lists of the included studies were searched by hand for additional citations. All results were exported to the literature management software EndNote for deduplication. The deduplicated results were imported into the Covidence systematic review management software to check title/abstract and full texts. All studies (title/abstract and full texts) were screened independently by two reviewers according to predefined criteria. Data extraction of all full texts was performed using a previously developed and tested extraction form. The extraction was repeated for 10% of the identified studies for quality assurance. Disagreements during the screening and extraction process were resolved by consensus.

Inclusion and exclusion criteria

The focus was on studies that evaluated the control of SLT at each level of jurisdiction to complement the knowledge collected for reporting on the implementation of WHO FCTC[4, 9, 17]. Our aim is to identify additional information to fill the gaps in reporting systems where data are not available. No restrictions were placed on the language or type of study. No review articles or modelling studies were included. Grey literature was not included due to lack of resources, e.g. ministerial reports, reports from international or social organisations.

We screened all included studies for reported affiliation, conflict of interest and funding to control for industry involvement. Only studies where the authors did not declare a conflict of interest or industry funding and where the authors were not affiliated with an industrial company were included.

Data extraction, coding and analyses

Studies were grouped by country, jurisdiction level (national, state, county, city), WHO FCTC articles and population groups studied. SLT policy effects were coded as positive, mixed or negative/no effect. The positive effect could be a reduction in consumption, a reduction in purchasing behaviour, knowledge of the regulations or compliance, depending on the instrument or focus studied. A mixed effect was coded if the results indicated a positive and a negative effect. No/negative effect was indicated if the results indicated that the policy had no effect or led to an increase in SLT use, or if a negative perception of the SLT control policy was reported.

If available in the included articles, information was provided on why the effect may have occurred or what influenced the outcome. Detailed information and the extraction sheet were published in protocol[23]. The extraction sheet was tested a priori. A narrative synthesis of the included studies is used to interpret and analyse the data.

RESULTS

A total of 1,011 articles were found in the database search and 35 articles were found in the reference list check. After duplicates were removed, 925 articles were screened by title and abstracts and 197 articles were included in the full text screening. The inclusion criteria were met by 40 articles (Appendix 2.1 Flow chart). One article had to be excluded from the full text screening due to a lack of language skills within the research team, as it was written in Japanese, and is marked accordingly in the flow chart. Within the articles, Pimple et al. 2014 [24], Ohsfeldt et al. 1997[25], McClelland et al. 2015[26] and Mumford et al. 2005[27] report on two instruments; Patja et al. 2009[28] report on two countries: Finland and Sweden, which are treated separately. Thus, the 40 articles refer to 41 studies. None of the full texts included reported industry involvement.

Countries covered, policy instruments evaluated in terms of WHO FCTC articles, and level of jurisdiction

The most important characteristics of the included studies are listed in appendix 2. A large number of studies were conducted in the USA (n=17[25-27, 29-42]), followed by India (n=15[24, 43-56]) and Finland (n=3[28, 57, 58]). One study each reported results from Bhutan[59], Myanmar[60], Sweden[28], Bangladesh[61], Norway[62] and South Africa[63]. One study analysed different member states of the EU[64]. According to the World Bank 64 classification, twenty-two studies were conducted in high-income countries, one in an upper-middle-income country and 18 in lower-middle-income countries. One study reporting results from different EU countries is not included in the classification. Study designs used were cross-sectional (n=16[24, 30, 32, 35, 36, 40, 44, 48-52, 56, 57, 59, 60]), observational (pre-post studies and interrupted time series analyses (n=5[33, 38, 41, 55, 61]), trend analyses (n=2[26, 42]), qualitative studies (n=3[47, 53, 64]) and mixed methods (n=2[45, 46]). Other designs used were snowball/network designs

(n=1[43]) and quantitative designs (n=3, quasi-experimental comparison[39], randomised controlled trial[34], quantitative descriptive study[62]). Secondary data were used in nine studies, with Finland and Sweden counted as separate studies in the Patel et al. article[25, 27-29, 31, 37, 58, 63].

A summary of all legislation referred to in the included studies is provided in Appendix 3 (Appendix 3). In addition, Appendix 4 matches the identified legislation with the instruments examined in the studies (e.g. health warnings, taxation, prohibition) to the FCTC articles (Appendix 4). In the USA, the largest number of studies refers to the Comprehensive Smokeless Tobacco Health Education Act of 1986 and its amendment from 2009 by the Family Smoking Prevention and Tobacco Control Act (n=8). One study analysed fiscal developments based on the Children's Health Insurance Program Reauthorization Act (CHIPRA) (2009) (n=1), and eight articles reported evaluation findings that analysed various US federal tobacco control policies but did not cite the relevant laws (n=8). A large number of studies from India examined the Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act (COTPA) (2003) (n=8), Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations (2011) (n=6) and Goods and Services Tax (GST) (2017) (n=1). Articles on South Africa, Bhutan, Finland, Myanmar, Sweden, Bangladesh and Norway analyse the national SLT policies of each country. The article on ten EU Member States looks at compliance with three EU directives: the 2001 European Union (EU) Tobacco Products Directive (TPD), Directive 2008/118/EC and Directive 2003/33/EC 63.

Some studies that assessed national policies were less concerned with the specific instruments used, but examined in general terms the control of availability, access and promotion of SLT; awareness, attitudes and perceived barriers to policy implementation; application, enforcement and compliance with existing national regulations; and their impact on the trends in SLT consumption[28, 44, 46, 59, 60, 63]. Studies that did not mention specific instruments are marked as 'general'. Other studies

assessed the impact of specific policy measures, such as the impact of tax regulations on SLT consumption[25-27, 30, 33, 40, 55], ban on gutkha and pan masala[24, 45, 47, 48, 50, 53], health warnings on SLT packaging[37, 43, 61], ban on sales near educational institutions[24, 49, 51, 52], ban on flavoured products[38, 39, 41], smoke-free law, including analyses of litter indicating SLT use[25-27] and one study each for a display ban[62], packaging and labelling issues[56], sales and advertising[32], marketing and sales[42], modified retail outlet environments[34], sales to minors[36], product availability in pharmacies[35], banning snus[58] and snuff[57], public expenditure on tobacco control programmes in general[31] and taxes on products sold online across countries, and advertising bans within the EU[64] (Appendix 4 Table 4. 1 and 4.2).

Legislative power, and thus the level at which policy resides, differs between countries. While in the federally organised states such as the USA and India many policies have been evaluated at the city and state level, in the other states policies have been analysed primarily at the national level. The public policies included in the scoping review refer to the city level (n=16), followed by the national level (n=12) and the state level (n=10), the district/county level (n=2) and a supranational level (EU) (n=1).

Reported effects of SLT control policies

Reported results vary in terms of impact on SLT consume behaviour. Impacts are highly context-specific, ranging from positive impacts in one state to no impacts in another. For some policies, there are positive and negative impacts in one country (Appendix 4 Table 4.2).

The impact of individual measures varies and overlaps within categories and countries. Positive impacts, i.e. increased awareness or reduction in consumer behaviour, were reported for the evaluation of general aspects of control measures such as knowledge, awareness and attitudes

towards the policy as a whole. Positive effects were also reported for health warnings, taxes, the ban on flavoured products, the ban on snuff and the ban on display with regard to SLT.

Mixed effects were reported for general aspects of the policies, health warnings, sales near educational institutions, bans on gutkha/pan masala, packaging and labelling, sales and advertising, marketing and sales, changes in the outlet environment, sales to minors, product availability in pharmacies and cross-country online taxes, and advertising within the EU.

In the included articles, no or negative impacts were reported for general aspects, health warnings, bans on sales near educational institutions, bans on gutkha/pan masala, smoke-free laws and snus bans (Appendix 4 Table 4.2).

India

The general evaluation of COTPA, the health warnings (Article 11), the ban on advertising and sales near educational institutions (Articles 13, 16), packaging and labelling (Article 11), the ban on gutkha and pan masala, and the taxation of SLT products (Article 6) were examined.

Studies evaluating COTPA in general and analysing the impact of the implementation of the Goods and Services Tax (GST) on prices and its influence on SLT consumption found positive impacts[55].

The positive impacts of COTPA evaluation were discussed in terms of the population studied. The study population was older than 50 years and had more than 10 years of schooling. It was discussed that the higher awareness was probably due to a medium socioeconomic status and a good perception of second-hand smoke as harmful, and that higher education might be associated with a positive attitude towards COTPA[44]. The results, although positive, may only apply to this population group.

Mixed effects were reported for regulations banning guthka and pan masala. The regulations are well known, but the products, especially those produced locally; continue to be available to regular

customers or in the black market at a higher price[24, 45, 47, 48, 50, 53]. Reddy et al. also reported that most gutkha consumers switch to other products (29.8% of the study population) and that newspapers were the main source of information about the ban (45.8% of the study population). However, they also reported high literacy levels in the study population[50]. Mixed effects were also found for the use of health warnings. While health warning regulations are followed for cigarettes, they are not followed for g gutkha[43].

No effects were found for the ban on sales near educational institutions. Although the ban is widely known, it is not implemented and rarely enforced. In addition, mobile vendors sell locally and are difficult to prosecute[24, 51, 52]. Furthermore, it is rarely known that violations can be reported. Selling to minors is accepted as a form of income. A study on COTPA among shopkeepers found that consumption and sales to minors are accepted, including as a form of income[46]. Barriers to the effectiveness of interventions mentioned include a lack of comprehensive information and awareness of the law, lack of economic alternatives especially for small-scale vendors, cultural acceptance of tobacco use, lack of political support, and the low priority given to combating SLT in general[46].

USA

In the USA, the ban on flavoured products had a positive impact on reducing SLT consumption (Article 9). The ban was accompanied by an extensive pre-ban information campaign and strong enforcement structures[38, 39, 41]. In addition, positive effects were found for high spending on public tobacco control programmes[31].

Mixed effects were reported for taxation, health warnings, advertising, sales and point-of-sale environment change measures, and evaluation of various tobacco control policies. In studies of whether subjects remembered health warnings, differences were found between income groups and

education levels, with higher education levels associated with higher awareness. Awareness of health warnings about SLT was lowest among those with low education and low annual household income[37]. For the sales and advertising tools, point-of-sale advertising and the use of predominant tobacco advertising displays were reported to be more prevalent in shops more likely to be frequented by youth. Snus was also sold to underage purchasers[32, 36]. One study evaluated several national control measures and reported positive effects on tobacco uptake, but no effects on current users. It suggests a mix of tobacco control measures (higher taxes on smokeless tobacco, higher minimum legal age for purchasing tobacco products, strict licensing requirements for tobacco products, restrictions on giving away free samples of tobacco products, posting of signs indicating the minimum age for purchasing tobacco products) would be effective in reducing SLT use among adolescent males[29].

Three studies examining higher taxes on SLT use and surveying students and young adults (≥25) reported no impact on SLT use[26, 27, 40]. One study found an increase in SLT use among males in parallel with an increase in cigarette taxes[40]. Two other studies reported that a higher cigarette tax was associated with a decrease in cigarette use in general, but also with a shift and product switching to SLT[25, 30]. 69% of pharmacies in Massachusetts were licensed to sell tobacco products (all cigarettes, moist snuff (53%), snus (14%)). This represented 9% of licensed tobacco retailers[35]. The introduction of a tobacco-free pharmacy concept would impact the majority of pharmacies in Massachusetts, as a variety of products are currently sold in licensed pharmacies.

Other countries

For the other countries, the picture is similarly diverse. In Finland[28] and South Africa[63], the evaluation of national tobacco control policies produced positive results. Both reported a decrease in SLT consumption, in South Africa even without excise tax. However, in South Africa, an

increase in consumption among black African women and a shift from the older to the youth population was noted[63]. In Norway, 98 % of shopkeepers complied with the ban on displaying snus[62].

Mixed impacts were reported for tobacco control policies in Myanmar and the online cross-country evaluation of the tax and advertising ban in the EU. Awareness of the policy is high in Myanmar. However, SLT products are still sold and there is a lack of awareness that non-compliance can result in a fine[60]. Although SLT products are banned in Finland, the prevalence of daily use among women is high and SLT products can be imported for personal use[28]. In the EU, taxation of tobacco products has been introduced and there is a ban on cross-border sales. However, cross-national online sales are still possible[64].

Population groups covered

The results of the evaluation of national policies to combat SLT consumption are diverse, and this also applies to the population groups included. The results are based on parts of the population (Table 3). The included studies report results for the following subgroups: students (n=8[26, 29, 31, 49, 52, 57, 58, 60]), retailers or vendors (n=8[32, 34, 36, 45, 46, 48, 50, 53]), user/former user (n=5[45, 47, 48, 50, 62]), shops, retail outlets (n=4[24, 42, 43, 56]), retail tobacco outlets (n=2[24, 42]), licensed pharmacies (n=1[35]) and school districts (n=1[51]). Sixteen articles did not further specify the population surveyed[26, 27, 30, 33, 35, 37-41, 54, 55, 59, 61, 63, 64]. Four studies reported results for males only[25, 27, 29, 47] or for both genders[28, 44, 50, 52]. Seventeen studies did not specify gender. Gender did not play a role in the 15 studies that used household data or analysed the implementation of advertising bans in outlets and shops (Table 3, Appendix 2).

(3) Gaps in SLT policy evaluation research

The current and comprehensive assessment of the WHO FCTC is based on the WHO Global Progress Reports on FCTC Implementation 2012, 2014, 2016. 2018; WHO reports on the global tobacco epidemic 2013, 2015, 2017, WHO NCI Monograph, Global Tobacco Surveillance System Data (including results from the Global Adult Tobacco Survey, Global Youth Tobacco Survey, Global Professions Student Survey, Global School Personnel Survey), country, regional and global smokeless tobacco control reports, tobacco control laws and regulations, and searches of PubMed for WHO FCTC-specific key terms. They provide a comprehensive overview of the current situation and the availability of regulations and data. However, the data are highly aggregated.

Policy evaluation studies complement this overview by answering questions at the national or regional level with a focus on the application of regulations. However, the data are sparse. Data are only available for India, the USA, Bangladesh, Bhutan, Finland, Myanmar, South Africa, Sweden and Norway. The data are also limited to Articles 6, 8, 9, 11, 13 and 16, and some of the Articles are only partially covered, such as Article 13, which deals with advertising and marketing. Sponsorship and advertising are not covered in the included studies. Another example is Article 16, which specifically prohibits the sale of SLT products near schools. Policy evaluations in India found that the problem of mobile vendors and the role of disadvantaged neighbourhoods influence the impact of policies on certain groups. These findings need to inform public policy making at the designated legislative level. However, data are not available for every level of jurisdiction and every article.

No national, federal, regional or municipal policy evaluation studies are available for Articles 7, 12, 14, 15, 17, 18, 19, 21 and 22 (Table 4).

Policy evaluation studies are the only data sources for the USA, as it has signed but not ratified the WHO FCTC and is therefore not included in the WHO FCTC data reports.

DISCUSSION

The aim of this scoping review was to identify: (1) countries for which studies evaluating public policies are available to complement existing WHO FCTC data, and (2) the level of jurisdiction, population groups and instruments studied, and the impact on consumption behaviour reported in these studies. Most studies have been conducted in India and the USA, which is consistent with the work of Mehrotra et al.[4] and Siddiqi et al.[17]. However, there is a lack of studies evaluating SLT policies at national and subnational levels in countries with high SLT prevalence (e.g. Sri Lanka, Nepal, Mauritania or Sudan, Norway, Croatia). Only for seven countries (Bangladesh, Bhutan, Myanmar, South Africa, Finland, Sweden, Norway) we found policy assessments in addition to WHO FCTC evaluations. For Articles 6, 9, 11, 13 and 16, there is overlap between the WHO FCTC article evaluation reported by Mehrotra et al. and the studies identified in our work[4]. However, national evaluation studies have assessed the impact of tobacco control policies using waste analysis, which could be used to fill this gap[25-27]. In addition, not all data are available for the same country and jurisdiction level, which limits the transferability of results. Except for the US and India, the results are not based on different affected populations such as consumers/former consumers, people in different socio-economic groups, illiterate people or retailers. This made it difficult to make predictions about the acceptance and compliance of individual measures in different population groups. Preliminary findings on how enforcement of the WHO FCTC might affect SLT sellers in Pakistan and their attitudes towards such measures can be found in a recently published paper[65]. Such findings are necessary to be prepared for the direct and indirect effects that the introduction of strict SLT control policies might have[66]. Further studies on public policy are needed that analyse the application and enforcement of control measures and the interaction between international regulations and national, federal and regional responsibilities. Research is needed on the impact of public policies on consumption patterns, problem awareness and behaviour

change. A recently published protocol[67] and the recent study published by Yadav et al. for India begin to fill these gaps[68]. Future research should also aim to analyse the role of industry participation in SLT public policy making.

The impacts found point to some interesting facts that should be considered in the development and evolution of policies to control SLT consumption and products. First, while higher taxation of tobacco products is an appropriate tool to reduce prevalence and consumption of tobacco products, product substitution should be considered for subgroups. Especially in countries with large local production (e.g. India) or cross-border purchasing habits (e.g. Finland), more information is needed on the perceptions and responses of different consumer groups, as well as on the impact and consequences of taxation, in order to align taxation with other instruments, such as strict licensing requirements for tobacco products, the display of signs indicating the minimum age for purchasing tobacco products, awareness-raising campaigns and campaigns to promote social norms and education. In addition, strong public support and enforcement capacity could strengthen regulatory approaches. Secondly, while policies may be widely known, external factors determine how regulations are administered and adhered to. For subgroups, e.g. people of low socio-economic status, lack of education, in deprived neighbourhoods, users and former users, shopkeepers and people who derive their income from the production, transport and sale of SLT products, education campaigns and support strategies should be discussed to promote compliance. However, to do this, more detailed data are needed to inform policy action.

Where smokeless tobacco regulation interacts with other policies, such as the regulation of 'gutkha' or 'pan masala' under the Food Safety and Standards Ordinance in India, such synergies should be harnessed and targeted.

Similar to previous work, the points indicate that policies need to be adapted and developed to suit the national and sub-national context. Simply transferring approaches and policy instruments may

not work. While much data is available, it is fragmented, relates to different levels of jurisdiction, to different target groups, and usually addresses only one aspect of control measures rather than interacting systems. Data at all levels of the evidence ladder need to be combined in a meaningful way to cover all level of jurisdictions. The most vulnerable groups and especially indirect effects need to be considered across jurisdictions. Data on subgroups, minorities, indirect effects, high- and low-income people in relation to attitudes or health warnings need to be collected and combined. Evaluation data linked to the process of policy development and implementation would also allow adjustments to be made if the impact does not materialise or even if it would be necessary to terminate certain approaches.

LIMITATION

Although the work follows the systematic approach of the Joanna Briggs Institute[21] and reports according to PRISMA-ScR[22], there are limitations. Due to licensing restrictions, the Embase database was not included. In addition, studies published in languages other than English or German were not included in the data extraction. This affected one study that was reported separately in the flow chart. In addition, studies on individual interventions that do not refer to public policies were not included. We may have missed some studies due to limitations to our search strategy which was developed with our research librarian. For example, studies that did not contain the specific search terms we used (e.g. regulation, control policy, public policy), the corresponding MeSH terms or controlled vocabulary (depending on the system used in the databases) in the title or abstract would not have been identified. We also did not include grey literature, as this would have exceeded the resources of the research team. Work from ministries and non-for-profit organisations is therefore not included as long as it has not been published in

peer-reviewed articles. Future work will have to fill this gap, which will also have to inform discussions on the methodological approach to results obtained from scientific and non-scientific literature.

In order to exclude any industry-sponsored studies, we have checked all included studies with regard to the stated affiliations, conflict of interests and funding. However, the information is based on the standards applicable at the time of publication. We have to trust the authors and the journal standards on this point, as it was not possible for the research team to check the information due to limited resources.

Due to the heterogeneity of study methodology and the nature of scoping reviews, no assessment of risk of bias was undertaken. Effects are only reported narratively.

CONCLUSION

More national and sub-national data is needed to support the development of evidence-informed policies based on existing regulations. The interplay between WHO FCTC regulations and jurisdictional levels affected at all levels should be analysed to identify mutually reinforcing systems or gaps. Much work needs to be done to develop best practice toolboxes, benchmarking systems and a combination of measures to develop strong and effective policies to combat SLT.

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Contribution following CRediT taxonomy of contributors

Conceptualization, SF, ZK, HZ; Methodology, SF, ZK, HZ; Investigation, SF, ZK, AF, AF, JF, TK, SU; Resources, LC; Writing original, review, editing: SF, ZK, AF, AF, JF, TK, SU, DO, KS, ZH; Funding Acquisition, SF, HZ, ZK, KS.

Competing Interests

None

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Data availability statement

Not applicable. All related data are attached to the publication as appendix.

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Figure captions

Figure 1: Jurisdiction covered within this scoping review

Tables

Table 1: Overview of countries with currently (Feb. 2021)[1] missing WHO FCTC Core Questionnaire 2020 data by signature and ratification.

Participant [2]	Signature	Ratification, Acceptance (A), Approval (AA), Formal confirmation (c), Accession (a), Succession (d)
Albania	2004	2006
Angola	2004	2007
Bahamas	2004	2009
Barbados	2004	2005
Bhutan	2003	2004
Botswana	2003	2005
Central African Republic	2004	2006
Chat		
Dominica	2004	2006
Equatorial Guinea		2005a
Eswatini	2004	2006
Ethiopia	2004	2014
Greece	2003	2006
Guinea	2004	2007
Israel	2003	2005
Kazakhstan	2004	2007
Kenya	2004	2004
Kyrgyzstan	2004	2006
Liberia	2004	2009
Maldives	2004	2004
Malta	2003	2003
Marshall Islands	2003	2004
Romania	2004	2006
Rwanda	2004	2005
Saint Kitts and Nevis	2004	2011
Saint Vincent and the Grenadines	2004	2010
San Marino	2003	2004
Slovenia	2003	2005
South Africa	2003	2005
Sri Lanka	2003	2003
Tajikistan		2013a
Timor-Leste	2004	2004
Uganda	2004	2007
Ukraine	2004	2006
United States of America	2004	
Uzbekistan		2012a
Yemen	2003	2007
Zambia		2008a

[1] https://fctc.who.int/who-fctc/reporting/parties-reporting-timeline; access: 14.06.2021

[2] Participants with full core questionnaire datasets not included.

Reporting procedure: Parties are required to report at intervals of two years and not later than six months before the next regular session of the Conference of the Parties. Countries that did not either sign or ratify the WHO FCTC are not obliged to report data and are not included.

Table 2: Overview of Policy instruments covered by country

Policy instruments covered, organized by WHO FCTC articles	Number of studies per policy instruments and country evaluated			
	India	USA	Other	Overall
Not covered by WHO FCTC				
General aspects	2	2	4	8
Gutkha and pan masala ban	6			6
Article 6 (Price and tax measures)				
Tax	1	5		7
Online cross-country Tax			1	1
Article 8 (Protection from exposure)				
Smoke-free places laws (free from residues of smokeless tobacco consumption)		3		3
Article 9 (Regulation of content)				
Ban (flavoured products)				3
Article 11 (Packaging and labelling)				
Health warnings	1	1	1	4
Packaging and labeling	1			1
Article 13 (Advertisement)				
Advertising&Sales		1		1
Marketing&Sales		1		1
Sales/Advertisement ban near educational institutions	4			4
Online cross-country advertisement			1	1
Display ban			1	1
Article 16 (Sale to and by minors)				
Provisions to change the point-of-sale environment		1		1
Sales to minors		1		1
Product availability in pharmacies		1		1
Snuff ban			1	1
Snus ban			1	1

Table 3: Study population covered per country

Study population per Country	General Population	Students	Retailers/Vendors	user/former user	Shops, retailer (facilities)	School districts	Gender reported in any of the studies
USA	x	x	x		X		x
India	x	x	x	x (gutkha)	X	X	x
Bangladesh	x						
Bhutan	x						
Myanmar		x					
South Africa							
Finland	x	x					x
Sweden	x						
Norway			x		X		

Table indicates study population covered, not frequency.

Table 4: Articles covered in Mehrotra et al. and the actual scoping review

WHO FCTC Article		Data at macro level (Mehrotra et al.) for countries covered by included studies	Data based on included national policy evaluation studies	Countries covered by included studies
PART II	**Objective, guiding principles and general obligations**			
3	Objective	x		
4	Guiding Principles			
5	General Obligations			
Part III	**Measures relating to the reduction of demand for tobacco**			
6	Price and tax measures to reduce the demand for tobacco	x (Bangladesh, India, Norway, South Africa)	x	India, USA, EU
7	Non-price measures to reduce the demand for tobacco			
8	Protection from exposure to tobacco smoke		x	USA
9	Regulation of the contents of tobacco products	x	x	USA
10	Regulation of tobacco product disclosures	x		
11	Packaging and labelling of tobacco products	x (Bangladesh, India, Myanmar, Norway, South Africa, Sweden)	x	India, USA, Bangladesh
12	Education, communication, training and public awareness	x		
13	Tobacco advertising, promotion and sponsorship	x (Bangladesh, Bhutan, Finland, India, Myanmar, Norway, South Africa, Sweden)	x	EU, India, USA
14	Demand reduction measures concerning tobacco dependence and cessation	x		
Part IV	**Measures relating to the reduction of the supply of tobacco**			

15	Illicit trade in tobacco products			
16	Sales to and by minor	x (Bhutan)	x	USA, India, Finland, Norway
17	Provision of support for economically viable alternative activities			
Part V	**Protection of the environment**			
18	Protection of the environment and the health of persons			
Part VI	**Questions related to liability**			
19	Liability			
PART VII	**Scientific and technical cooperation and communication of information**			
20	Research, surveillance and exchange of information	x		
21	Reporting and exchange of information			
22	Cooperation in the scientific, technical and legal fields and provision of related expertise			

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