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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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11
12 6 **Abstract**
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15 7 **Objective** – The implementation of smokeless tobacco control policies lags behind those for
16
17 8 smoking. This scoping review summarises the studies that evaluated public policies on smokeless
18
19 9 tobacco regulation (SLT) and provides an overview of the jurisdictional level, target groups and
20
21 10 policy instruments.
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23

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25 11 **Methods** – Seven databases were systematically searched for studies reporting on public policies
26
27 12 regulating SLT. All studies were independently screened by two reviewers. Data extraction was
28
29 13 performed using a predefined extraction form. Extraction was replicated for 10% of the identified
30
31 14 studies for quality assurance. A narrative synthesis of the included studies was used to analyse and
32
33 15 interpret the data. The protocol was published beforehand with the OSF.
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37 16 **Results** – 40 articles comprising 41 studies were included. Most of the studies reported in the
38
39 17 articles were conducted in the USA (n=17) or India (n=14). Most studies reported outcomes for
40
41 18 students (n=8), retailers/sellers (n=8) and users/former users (n=5). The impact of public policies
42
43 19 on smokeless tobacco use in general was most frequently assessed (n=9), followed by the impact
44
45 20 of taxes (n=7), product bans (n=6), sales/advertising bans near educational institutions (n=4) and
46
47 21 health warnings (n=3) on consumer behaviour.
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49

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51 22 **Conclusions** – There are major gaps in the evaluation of smokeless tobacco regulation studies that
52
53 23 need to be filled by further research to understand the observed outcomes. WHO reporting on
54
55 24 FCTC implementation should be linked to studies evaluating smokeless tobacco control measures
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1 at all levels of jurisdictions and in countries that are not members of the WHO FCTC or do not
2 provide data.

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

8 **Implication**

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

22 **INTRODUCTION**

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

1 Asia, SLT is also widespread in Central Asia, the Scandinavian countries, North America and many
2 African countries (e.g. Nigeria, Ghana, Algeria, Cameroon, Chad, Senegal, Sudan and South
3 Africa)^{3,4}. SLT use is a risk factor for cancers of the head and neck⁵ and is associated, for example,
4 with cardiovascular disease and adverse reproductive outcomes such as low birth weight, preterm
5 and stillbirths^{4,6}. According to the Global Burden of Disease study, there were 55,600 deaths (95%
6 UI 43,100-68,800) due to SLT in 2019, of which 46,000 (35,500-58,000) were in South Asia⁷.
7 The WHO Framework Convention on Tobacco Control (FCTC) was adopted by the World Health
8 Assembly in 2003 and was open for signature between June 2003 to June 2004, during which time
9 168 countries signed the treaty⁸. It provides a comprehensive strategy to combat the tobacco
10 epidemic, including SLT (Appendix 5)⁹. The FCTC is WHO's first global public health treaty¹⁰. It
11 is legally the international community's most powerful tobacco control instrument¹¹. The
12 Convention is binding on countries through ratification, acceptance, approval, formal confirmation
13 or accession¹². The WHO FCTC must be transposed into national law, applied and enforced to
14 become part of the national law of a sovereign state. This includes comparing existing legislation
15 with the treaty provisions, examining administrative structures and adapting them where necessary,
16 and developing administrative and technical guidance for its application¹³. Currently, 182 Parties,
17 whose populations represent 90% of the world's population, have signed the Convention¹⁴. Existing
18 reviews of the impact of the FCTC indicate promising approaches to reducing tobacco use^{9, 15}.
19 Although SLT products fall within the policy framework of the WHO FCTC, they have not
20 received the same priority as tobacco among FCTC Parties. Only 34 out of 180 Parties (as of 2019)
21 tax or report taxing SLT products, six Parties measure SLT product content and constituents, and
22 41 of the Parties require pictorial health warnings on products. Only a few Parties collect or present
23 data on smokeless tobacco use through global or national surveillance mechanisms (e.g. Global

1 Tobacco Surveillance System and WHO STEPwise) or have comprehensive bans on advertising,
2 promotion or sponsorship of SLT⁴.

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

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

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

3 **METHODS**

4 The scoping review follows a similar approach to a systematic review¹⁸⁻²¹. The Preferred Reporting
5 Items for Systematic Reviews and Meta-Analysis: extension for Scoping Reviews (PRISMA-SCR
6 and flow chart) were used to illustrate the flow of information through the different stages of the
7 scoping review²². A study protocol was published in advance²³.

9 **Search strategy and information sources**

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

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

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5 2 **Inclusion and exclusion criteria**
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8 3 The focus was on studies that evaluated the control of SLT at each level of jurisdiction to
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10 4 complement the knowledge collected for reporting on the implementation of WHO FCTC^{4, 9, 17}.
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12 5 Our aim is to identify additional information to fill the gaps in reporting systems where data are
13
14 6 not available. No restrictions were placed on the language or type of study. No review articles or
15
16 7 modelling studies were included. Grey literature was not included due to lack of resources, e.g.
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18 8 ministerial reports, reports from international or social organisations.

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21 9 We screened all included studies for reported affiliation, conflict of interest and funding to control
22
23 10 for industry involvement. Only studies where the authors did not declare a conflict of interest or
24
25 11 industry funding and where the authors were not affiliated with an industrial company were
26
27 12 included.
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33 14 **Data extraction, coding and analyses**

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35 15 Studies were grouped by country, jurisdiction level (national, state, county, city), WHO FCTC
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37 16 articles and population groups studied. SLT policy effects were coded as positive, mixed or
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39 17 negative/no effect. The positive effect could be a reduction in consumption, a reduction in
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41 18 purchasing behaviour, knowledge of the regulations or compliance, depending on the instrument
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43 19 or focus studied. A mixed effect was coded if the results indicated a positive and a negative effect.
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45 20 No/negative effect was indicated if the results indicated that the policy had no effect or led to an
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47 21 increase in SLT use, or if a negative perception of the SLT control policy was reported.
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49 22 If available in the included articles, information was provided on why the effect may have occurred
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51 23 or what influenced the outcome. Detailed information and the extraction sheet were published in
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1 protocol²³. The extraction sheet was tested a priori. A narrative synthesis of the included studies is
2 used to interpret and analyse the data.

4 RESULTS

5 A total of 1,011 articles were found in the database search and 35 articles were found in the
6 reference list check. After duplicates were removed, 925 articles were screened by title and
7 abstracts and 197 articles were included in the full text screening. The inclusion criteria were met
8 by 40 articles (Appendix 2.1 Flow chart). One article had to be excluded from the full text screening
9 due to a lack of language skills within the research team, as it was written in Japanese, and is
10 marked accordingly in the flow chart. Within the articles, Pimple et al. 2014²⁴, Ohsfeldt et al.
11 1997²⁵, McClelland et al. 2015²⁶ and Mumford et al. 2005²⁷ report on two instruments; Patja et al.
12 2009²⁸ report on two countries: Finland and Sweden, which are treated separately. Thus, the 40
13 articles refer to 41 studies. None of the full texts included reported industry involvement.

15 Countries covered, policy instruments evaluated in terms of WHO FCTC articles, and level 16 of jurisdiction

17 The most important characteristics of the included studies are listed in appendix 2. A large number
18 of studies were conducted in the USA (n=17^{25-27, 29-42}), followed by India (n=15^{24, 43-56}) and Finland
19 (n=3^{28, 57, 58}). One study each reported results from Bhutan⁵⁹, Myanmar⁶⁰, Sweden²⁸, Bangladesh⁶¹,
20 Norway⁶² and South Africa⁶³. One study analysed different member states of the EU⁶⁴. According
21 to the World Bank 64 classification, twenty-two studies were conducted in high-income countries,
22 one in an upper-middle-income country and 18 in lower-middle-income countries. One study
23 reporting results from different EU countries is not included in the classification. Study designs
24 used were cross-sectional (n=16^{24, 30, 32, 35, 36, 40, 44, 48-52, 56, 57, 59, 60}), observational (pre-post studies

1 and interrupted time series analyses (n=5^{33, 38, 41, 55, 61}), trend analyses (n=2^{26, 42}), qualitative studies
2 (n=3^{47, 53, 64}) and mixed methods (n=2^{45, 46}). Other designs used were snowball/network designs
3 (n=1⁴³) and quantitative designs (n=3, quasi-experimental comparison³⁹, randomised controlled
4 trial³⁴, quantitative descriptive study⁶²). Secondary data were used in nine studies, with Finland and
5 Sweden counted as separate studies in the Patel et al. article^{25, 27-29, 31, 37, 58, 63}.

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

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

1 compliance with existing national regulations; and their impact on the trends in SLT consumption²⁸,
2 44, 46, 59, 60, 63. Studies that did not mention specific instruments are marked as 'general'. Other studies
3 assessed the impact of specific policy measures, such as the impact of tax regulations on SLT
4 consumption^{25-27, 30, 33, 40, 55}, ban on gutkha and pan masala^{24, 45, 47, 48, 50, 53}, health warnings on SLT
5 packaging^{37, 43, 61}, ban on sales near educational institutions^{24, 49, 51, 52}, ban on flavoured products³⁸,
6 ^{39, 41}, smoke-free law, including analyses of litter indicating SLT use²⁵⁻²⁷ and one study each for a
7 display ban⁶², packaging and labelling issues⁵⁶, sales and advertising³², marketing and sales⁴²,
8 modified retail outlet environments³⁴, sales to minors³⁶, product availability in pharmacies³⁵,
9 banning snus⁵⁸ and snuff⁵⁷, public expenditure on tobacco control programmes in general³¹ and
10 taxes on products sold online across countries, and advertising bans within the EU⁶⁴ (Appendix 4
11 Table 4. 1 and 4.2).

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

19 **Reported effects of SLT control policies**

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

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

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3 1 evaluation of general aspects of control measures such as knowledge, awareness and attitudes
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5 2 towards the policy as a whole. Positive effects were also reported for health warnings, taxes, the
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7 3 ban on flavoured products, the ban on snuff and the ban on display with regard to SLT.
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10 4 Mixed effects were reported for general aspects of the policies, health warnings, sales near
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12 5 educational institutions, bans on gutkha/pan masala, packaging and labelling, sales and advertising,
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14 6 marketing and sales, changes in the outlet environment, sales to minors, product availability in
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16 7 pharmacies and cross-country online taxes, and advertising within the EU.
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19 8 In the included articles, no or negative impacts were reported for general aspects, health warnings,
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21 9 bans on sales near educational institutions, bans on gutkha/pan masala, smoke-free laws and snus
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24 10 bans (Appendix 4 Table 4.2).
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29 12 **India**

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31 13 The general evaluation of COTPA, the health warnings (Article 11), the ban on advertising and
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33 14 sales near educational institutions (Articles 13, 16), packaging and labelling (Article 11), the ban
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35 15 on gutkha and pan masala, and the taxation of SLT products (Article 6) were examined.
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38 16 Studies evaluating COTPA in general and analysing the impact of the implementation of the Goods
39
40 17 and Services Tax (GST) on prices and its influence on SLT consumption found positive impacts⁵⁵.
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43 18 The positive impacts of COTPA evaluation were discussed in terms of the population studied. The
44
45 19 study population was older than 50 years and had more than 10 years of schooling. It was discussed
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47 20 that the higher awareness was probably due to a medium socioeconomic status and a good
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49 21 perception of second-hand smoke as harmful, and that higher education might be associated with
50
51 22 a positive attitude towards COTPA⁴⁴. The results, although positive, may only apply to this
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54 23 population group.
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1 Mixed effects were reported for regulations banning guthka and pan masala. The regulations are
2 well known, but the products, especially those produced locally; continue to be available to regular
3 customers or in the black market at a higher price^{24, 45, 47, 48, 50, 53}. Reddy et al. also reported that
4 most guthka consumers switch to other products (29.8% of the study population) and that
5 newspapers were the main source of information about the ban (45.8% of the study population).
6 However, they also reported high literacy levels in the study population⁵⁰. Mixed effects were also
7 found for the use of health warnings. While health warning regulations are followed for cigarettes,
8 they are not followed for guthka⁴³.

9 No effects were found for the ban on sales near educational institutions. Although the ban is widely
10 known, it is not implemented and rarely enforced. In addition, mobile vendors sell locally and are
11 difficult to prosecute^{24, 51, 52}. Furthermore, it is rarely known that violations can be reported. Selling
12 to minors is accepted as a form of income. A study on COTPA among shopkeepers found that
13 consumption and sales to minors are accepted, including as a form of income⁴⁶. Barriers to the
14 effectiveness of interventions mentioned include a lack of comprehensive information and
15 awareness of the law, lack of economic alternatives especially for small-scale vendors, cultural
16 acceptance of tobacco use, lack of political support, and the low priority given to combating SLT
17 in general⁴⁶.

19 USA

20 In the USA, the ban on flavoured products had a positive impact on reducing SLT consumption
21 (Article 9). The ban was accompanied by an extensive pre-ban information campaign and strong
22 enforcement structures^{38, 39, 41}. In addition, positive effects were found for high spending on public
23 tobacco control programmes³¹.

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3 1 Mixed effects were reported for taxation, health warnings, advertising, sales and point-of-sale
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5 2 environment change measures, and evaluation of various tobacco control policies. In studies of
6
7 3 whether subjects remembered health warnings, differences were found between income groups and
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9 4 education levels, with higher education levels associated with higher awareness. Awareness of
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11 5 health warnings about SLT was lowest among those with low education and low annual household
12
13 6 income³⁷. For the sales and advertising tools, point-of-sale advertising and the use of predominant
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15 7 tobacco advertising displays were reported to be more prevalent in shops more likely to be
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17 8 frequented by youth. Snus was also sold to underage purchasers^{32, 36}. One study evaluated several
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19 9 national control measures and reported positive effects on tobacco uptake, but no effects on current
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21 10 users. It suggests a mix of tobacco control measures (higher taxes on smokeless tobacco, higher
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23 11 minimum legal age for purchasing tobacco products, strict licensing requirements for tobacco
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25 12 products, restrictions on giving away free samples of tobacco products, posting of signs indicating
26
27 13 the minimum age for purchasing tobacco products) would be effective in reducing SLT use among
28
29 14 adolescent males²⁹.

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35 15 Three studies examining higher taxes on SLT use and surveying students and young adults (≥ 25)
36
37 16 reported no impact on SLT use^{26, 27, 40}. One study found an increase in SLT use among males in
38
39 17 parallel with an increase in cigarette taxes⁴⁰. Two other studies reported that a higher cigarette tax
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41 18 was associated with a decrease in cigarette use in general, but also with a shift and product
42
43 19 switching to SLT^{25, 30}. 69% of pharmacies in Massachusetts were licensed to sell tobacco products
44
45 20 (all cigarettes, moist snuff (53%), snus (14%)). This represented 9% of licensed tobacco retailers³⁵.
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47 21 The introduction of a tobacco-free pharmacy concept would impact the majority of pharmacies in
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49 22 Massachusetts, as a variety of products are currently sold in licensed pharmacies.
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56 24 **Other countries**

1 For the other countries, the picture is similarly diverse. In Finland²⁸ and South Africa⁶³, the
2 evaluation of national tobacco control policies produced positive results. Both reported a decrease
3 in SLT consumption, in South Africa even without excise tax. However, in South Africa, an
4 increase in consumption among black African women and a shift from the older to the youth
5 population was noted⁶³. In Norway, 98 % of shopkeepers complied with the ban on displaying
6 snus⁶².

7 Mixed impacts were reported for tobacco control policies in Myanmar and the online cross-country
8 evaluation of the tax and advertising ban in the EU. Awareness of the policy is high in Myanmar.
9 However, SLT products are still sold and there is a lack of awareness that non-compliance can
10 result in a fine⁶⁰. Although SLT products are banned in Finland, the prevalence of daily use among
11 women is high and SLT products can be imported for personal use²⁸. In the EU, taxation of tobacco
12 products has been introduced and there is a ban on cross-border sales. However, cross-national
13 online sales are still possible⁶⁴.

15 **Population groups covered**

16 The results of the evaluation of national policies to combat SLT consumption are diverse, and this
17 also applies to the population groups included. The results are based on parts of the population
18 (Table 3). The included studies report results for the following subgroups: students (n=8^{26, 29, 31, 49,}
19 ^{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,
20 retail outlets (n=4^{24, 42, 43, 56}), retail tobacco outlets (n=2^{24, 42}), licensed pharmacies (n=1³⁵) and
21 school districts (n=1⁵¹). Sixteen articles did not further specify the population surveyed^{26, 27, 30, 33,}
22 ^{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,}
23 ^{44, 50, 52}. Seventeen studies did not specify gender. Gender did not play a role in the 15 studies that

1 used household data or analysed the implementation of advertising bans in outlets and shops (Table
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4 3, Appendix 2).
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10 **(3) Gaps in SLT policy evaluation research**

11
12 5 The current and comprehensive assessment of the WHO FCTC is based on the WHO Global
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14 6 Progress Reports on FCTC Implementation 2012, 2014, 2016. 2018; WHO reports on the global
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16 7 tobacco epidemic 2013, 2015, 2017, WHO NCI Monograph, Global Tobacco Surveillance System
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18 8 Data (including results from the Global Adult Tobacco Survey, Global Youth Tobacco Survey,
19
20 9 Global Professions Student Survey, Global School Personnel Survey), country, regional and global
21
22 10 smokeless tobacco control reports, tobacco control laws and regulations, and searches of PubMed
23
24 11 for WHO FCTC-specific key terms. They provide a comprehensive overview of the current
25
26 12 situation and the availability of regulations and data. However, the data are highly aggregated.
27
28 13 Policy evaluation studies complement this overview by answering questions at the national or
29
30 14 regional level with a focus on the application of regulations. However, the data are sparse. Data are
31
32 15 only available for India, the USA, Bangladesh, Bhutan, Finland, Myanmar, South Africa, Sweden
33
34 16 and Norway. The data are also limited to Articles 6, 8, 9, 11, 13 and 16, and some of the Articles
35
36 17 are only partially covered, such as Article 13, which deals with advertising and marketing.
37
38 18 Sponsorship and advertising are not covered in the included studies. Another example is Article
39
40 19 16, which specifically prohibits the sale of SLT products near schools. Policy evaluations in India
41
42 20 found that the problem of mobile vendors and the role of disadvantaged neighbourhoods influence
43
44 21 the impact of policies on certain groups. These findings need to inform public policy making at the
45
46 22 designated legislative level. However, data are not available for every level of jurisdiction and
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48 23 every article.
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3 1 No national, federal, regional or municipal policy evaluation studies are available for Articles 7,
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5 2 12, 14, 15, 17, 18, 19, 21 and 22 (Table 4).
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7
8 3 Policy evaluation studies are the only data sources for the USA, as it has signed but not ratified the
9
10 4 WHO FCTC and is therefore not included in the WHO FCTC data reports.
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12 5

14 6 **DISCUSSION**

17 7 The aim of this scoping review was to identify: (1) countries for which studies evaluating public
18
19 8 policies are available to complement existing WHO FCTC data, and (2) the level of jurisdiction,
20
21 9 population groups and instruments studied, and the impact on consumption behaviour reported in
22
23 10 these studies. Most studies have been conducted in India and the USA, which is consistent with the
24
25 11 work of Mehrotra et al.⁴ and Siddiqi et al.¹⁷. However, there is a lack of studies evaluating SLT
26
27 12 policies at national and subnational levels in countries with high SLT prevalence (e.g. Sri Lanka,
28
29 13 Nepal, Mauritania or Sudan, Norway, Croatia). Only for seven countries (Bangladesh, Bhutan,
30
31 14 Myanmar, South Africa, Finland, Sweden, Norway) we found policy assessments in addition to
32
33 15 WHO FCTC evaluations. For Articles 6, 9, 11, 13 and 16, there is overlap between the WHO FCTC
34
35 16 article evaluation reported by Mehrotra et al. and the studies identified in our work⁴. However,
36
37 17 national evaluation studies have assessed the impact of tobacco control policies using waste
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39 18 analysis, which could be used to fill this gap²⁵⁻²⁷. In addition, not all data are available for the same
40
41 19 country and jurisdiction level, which limits the transferability of results. Except for the US and
42
43 20 India, the results are not based on different affected populations such as consumers/former
44
45 21 consumers, people in different socio-economic groups, illiterate people or retailers. This made it
46
47 22 difficult to make predictions about the acceptance and compliance of individual measures in
48
49 23 different population groups. Preliminary findings on how enforcement of the WHO FCTC might
50
51 24 affect SLT sellers in Pakistan and their attitudes towards such measures can be found in a recently
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1 published paper⁶⁵. Such findings are necessary to be prepared for the direct and indirect effects that
2 the introduction of strict SLT control policies might have⁶⁶. Further studies on public policy are
3 needed that analyse the application and enforcement of control measures and the interaction
4 between international regulations and national, federal and regional responsibilities. Research is
5 needed on the impact of public policies on consumption patterns, problem awareness and behaviour
6 change. A recently published protocol⁶⁷ and the recent study published by Yadav et al. for India
7 begin to fill these gaps⁶⁸. Future research should also aim to analyse the role of industry
8 participation in SLT public policy making.

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

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

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

17 **LIMITATION**

18 Although the work follows the systematic approach of the Joanna Briggs Institute²¹ and reports
19 according to PRISMA-ScR²², there are limitations. Due to licensing restrictions, the Embase
20 database was not included. In addition, studies published in languages other than English or
21 German were not included in the data extraction. This affected one study that was reported
22 separately in the flow chart. In addition, studies on individual interventions that do not refer to
23 public policies were not included. We may have missed some studies due to limitations to our
24 search strategy which was developed with our research librarian. For example, studies that did

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

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

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

17 **CONCLUSION**

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

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7
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14
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16 7
17 8 Conceptualization, SF, ZK, HZ; Methodology, SF, ZK, HZ; Investigation, SF, ZK, AF, AF, JF,
18 9 TK, SU; Resources, LC; Writing original, review, editing: SF, ZK, AF, AF, JF, TK, SU, DO, KS,
19
20 10 ZH; Funding Acquisition, SF, HZ, ZK, KS.
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25 11
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28
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32

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49 21
50 22 **Data availability statement**

51 23 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

For Peer Review

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3 **1 Tables**
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11 **Table 1: Overview of countries with currently (Feb. 2021)¹ missing WHO FCTC Core**
12 **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

9 ¹ <https://fctc.who.int/who-fctc/reporting/parties-reporting-timeline>; access: 14.06.2021

10 ² Participants with full core questionnaire datasets not included.

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

1 **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

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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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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" OR "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						
5	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
10	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
14	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
18	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
21	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
25	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
30	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
37	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

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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

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3	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
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14	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	
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19	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	
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23	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
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26	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	
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29	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	
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34	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)
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									smokeless consumption, especially girls				
5	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	
8	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		
12	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	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.	
22	Seidenberg et al. 2013	USA state	Massachusetts	Product availability in pharmacies	16	Licensed pharmacies				Cross-sectional study	Excise taxes, on either cigarettes or SLT products unrelated to odds of current use	69% had a license to sell tobacco products (all cigarettes, moist snuff (53%), snus (14%))	Made up 9% of licensed tobacco retailers
26	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		
29	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	

1 2 3 4 5 6 7 8 9 10	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)
11 12 13 14	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
15 16	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	
17 18 19	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
20 21 22	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
23 24 25	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	
26 27 28 29	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)
30 31	Patja et al. 2009	Sweden national	Swedish Tobacco Control Act (TCA), 1993	General							
32 33 34 35 36 37 38 39 40 41 42 43 44 45 46	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	

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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.

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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, 2003 (Act No. 34 of 2003) (COTPA), 2003	<p>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.</p> <p>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).</p> <p>https://www.tobaccocontrollaws.org/</p>
	Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011	<p>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."</p> <p>https://www.tobaccocontrollaws.org/</p>
	Goods and Services Tax (GST), 2017	<p>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</p> <p>Tobacco: Part of GST but power to levy additional excise duty with Central Government</p> <p>http://www.gstcouncil.gov.in</p>

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USA	Comprehensive Smokeless Tobacco Health Education Act of 1986	<p>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.</p> <p>https://www.ftc.gov/enforcement/statutes/comprehensive-smokeless-tobacco-health-education-act-1986</p>
	Amendment in 2009 by the Family Smoking Prevention and Tobacco Control Act	<p>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.</p> <p>https://www.publichealthlawcenter.org/sites/default/files/resources/tclc-fs-global-flavored-regs-2015.pdf</p>
	Children’s Health Insurance Program Reauthorization Act (CHIPRA), 2009	<p>CHIPRA increased federal excise tax rates on tobacco products, effective April 1, 2009, to fund the Children's Health Insurance Program (CHIP)</p> <p>https://www.everycrsreport.com/reports/R40130.html</p>
South Africa	Tobacco Products Control (TPC) Act of 1993 (Act 83 of 1993)	<p>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</p>

		<p>sponsorship).</p> <p>It was amended by General Law Fifth Amendment Act 157 of 1993, Tobacco Products 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.</p> <p>https://www.tobaccocontrollaws.org/legislation/country/south-africa/laws</p>
Bhutan	Tobacco Control Act, 2010	<p>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.</p> <p>https://www.tobaccocontrollaws.org/legislation/country/bhutan/summary</p>
Myanmar	Control of Smoking and Consumption of Tobacco Product Law (Tobacco Control Law; TCL), 2006	<p>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.</p> <p>https://www.tobaccocontrollaws.org/legislation/country/myanmar/summary</p>
Finland	Tobacco Control Act Amendment (TCAA), 1995	<p>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.</p>

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		<p>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)</p> <p>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, Korhonen HJ, Uutel A, et al. Puska P, Elovainio L, Vertio H. Anti-smoking policy in Finland, Smokefree Europe: A Forum for Networks, 1997</p>
Swedish	Swedish Tobacco Control Act (TCA), 1993	<p>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.</p> <p>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.</p> <p>https://www.tobaccocontrollaws.org/legislation/country/sweden/summary</p>
EU	Directive	Directive 2008/118/EC lays down general arrangements in relation to excise duty which is levied directly or indirectly on the

	<p>2008/118/EC & Directive 2003/33/EC (tobacco advertising across EU countries)</p>	<p>consumption of the following goods (hereinafter 'excise goods'): (c) manufactured tobacco covered by Directives 95/59/EC, 92/79/EEC and 92/80/EEC.</p> <p>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</p> <p>https://eur-lex.europa.eu/homepage.html</p>
Bangladesh	<p>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)</p>	<p>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.</p> <p>https://www.tobaccocontrollaws.org/legislation/country/bangladesh/laws</p>
Norway	<p>Tobacco Control Act, 1973</p>	<p>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.</p> <p>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</p>

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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.

For Peer Review

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 FTC 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

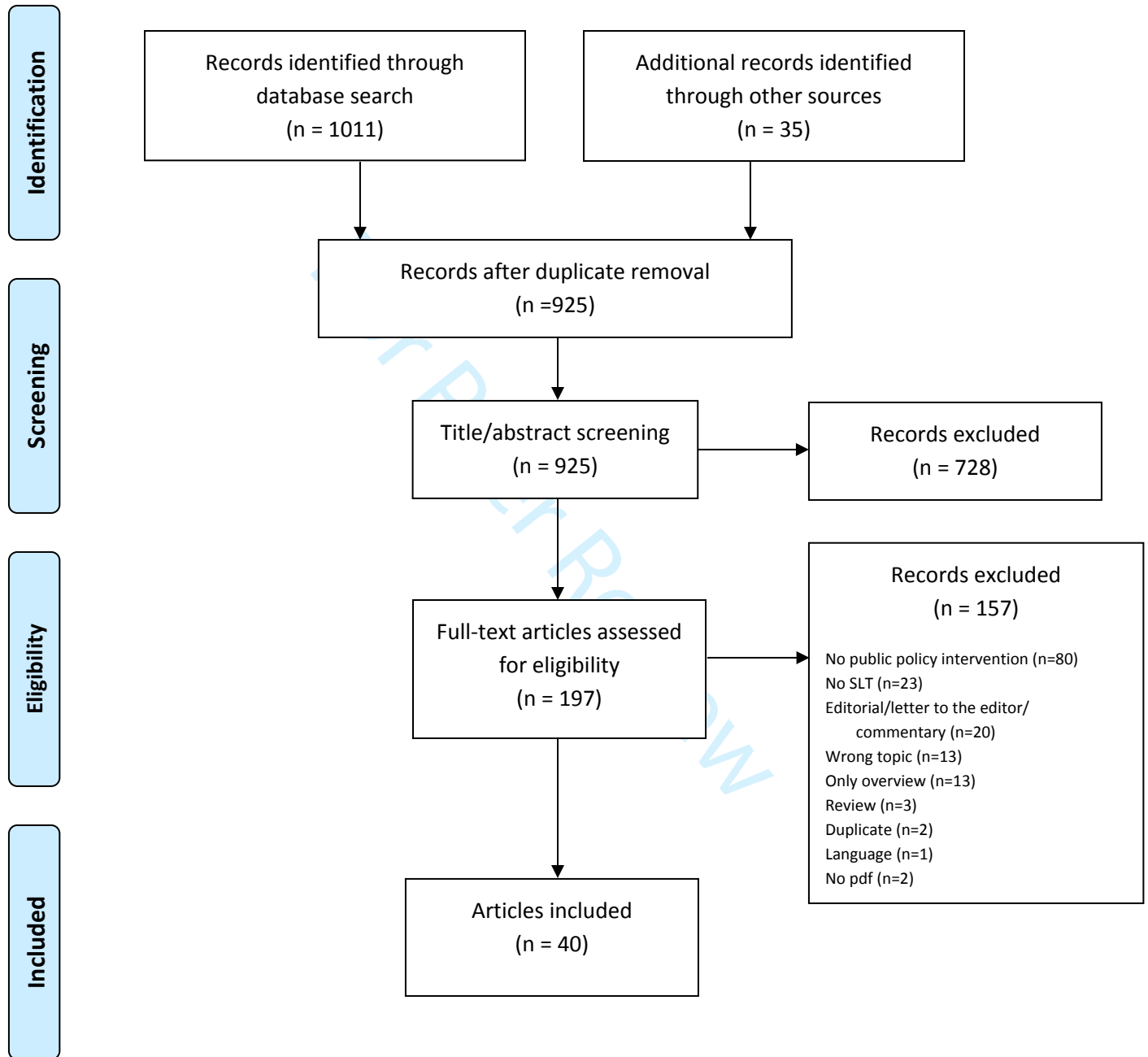
* Studies analysing smoke-free places evaluated the litter, which indicated the consumption of smokeless tobacco.

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	Lobbying/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	

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3	Part V	Protection of the environment		
4		18	Protection of the environment and the health of persons	Environment
5				Protection of environment and the health of persons in respect to tobacco cultivation and manufacture
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9	Part VI	Questions related to liability		
10		19	Liability	Regulation
11				Taking legislative action or promoting their existing laws, where necessary, to deal with criminal and civil liability
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16	Part VII	Scientific and technical cooperation and communication of information		
17		20	Research, surveillance and exchange of information	Research
18				Tobacco-related research and information sharing among the parties.
19		21	Reporting and exchange of information	Research
20				Tobacco-related research and information sharing among the parties.
21		22	Cooperation in the scientific, technical and legal fields and provision of related expertise	Research
22				Tobacco-related research and information sharing among the parties.
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26	Part VIII	Institutional arrangements and financial resources		
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29	Part IX-X			
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31		28-29	Development of the convention	
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37	Part XI	Final provision		
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Appendix 2.1: Flow diagram



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4 1 **Scoping review of existing evaluations of smokeless tobacco control policies: What is known**
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6 2 **about countries covered, level of jurisdictions, target groups studied and instruments**
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8 3 **evaluated?**
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14 5 **Authors and affiliations**
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12 6 **Abstract**
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15 7 **Objective** – The implementation of smokeless tobacco control policies lags behind those for
16 8 smoking. This scoping review summarises the studies that evaluated public policies on smokeless
17 9 tobacco regulation (SLT) and provides an overview of the jurisdictional level, target groups and
18 10 policy instruments.
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25 11 **Methods** – Seven databases were systematically searched for studies reporting on public policies
26 12 regulating SLT. All studies were independently screened by two reviewers. Data extraction was
27 13 performed using a predefined extraction form. Extraction was replicated for 10% of the identified
28 14 studies for quality assurance. A narrative synthesis of the included studies was used to analyse and
29 15 interpret the data. The protocol was published beforehand with the OSF.
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37 16 **Results** – 40 articles comprising 41 studies were included. Most of the studies reported in the
38 17 articles were conducted in the USA (n=17) or India (n=14). Most studies reported outcomes for
39 18 students (n=8), retailers/sellers (n=8) and users/former users (n=5). The impact of public policies
40 19 on smokeless tobacco use in general was most frequently assessed (n=9), followed by the impact
41 20 of taxes (n=7), product bans (n=6), sales/advertising bans near educational institutions (n=4) and
42 21 health warnings (n=3) on consumer behaviour.
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50 22 **Conclusions** – There are major gaps in the evaluation of smokeless tobacco regulation studies that
51 23 need to be filled by further research to understand the observed outcomes. WHO reporting on
52 24 FCTC implementation should be linked to studies evaluating smokeless tobacco control measures
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3 1 at all levels of jurisdictions and in countries that are not members of the WHO FCTC or do not
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5 2 provide data.
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10 4 Keywords: Smokeless tobacco, tobacco control policy, national control policy, policy evaluation,
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12 5 WHO FCTC, policy implementation
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19 8 **Implication**

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21 9 Large gaps in the evaluation of SLT control policies exists. For some countries, WHO FCTC
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23 10 evaluations are available for different levels of jurisdictions. In countries with a strong federal
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25 11 structure, there is a lack of data that goes beyond the national level to provide a more detailed look
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27 12 at compliance, indirect effects or implementation gaps. More research is needed at all levels of
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29 13 jurisdictions, that add to the work of the WHO to understand what works for which target group,
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31 14 how the different levels of jurisdiction interact, how the real-world context can be incorporated,
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33 15 and what indirect effects may occur.
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52 22 **INTRODUCTION**

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54 23 Smokeless tobacco (SLT) is used by more than 300 million people worldwide^{1,2}. The geographical
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56 24 distribution of SLT use varies widely. While most SLT users (82 %) live in South and South-East
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3 1 Asia, SLT is also widespread in Central Asia, the Scandinavian countries, North America and many
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5 2 African countries (e.g. Nigeria, Ghana, Algeria, Cameroon, Chad, Senegal, Sudan and South
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7 3 Africa)^{3, 4}. SLT use is a risk factor for cancers of the head and neck⁵ and is associated, for example,
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9 4 with cardiovascular disease and adverse reproductive outcomes such as low birth weight, preterm
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11 5 and stillbirths^{4, 6}. According to the Global Burden of Disease study, there were 55,600 deaths (95%
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13 6 UI 43,100-68,800) due to SLT in 2019, of which 46,000 (35,500-58,000) were in South Asia⁷.
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17 7 The WHO Framework Convention on Tobacco Control (FCTC) was adopted by the World Health
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19 8 Assembly in 2003 and was open for signature between June 2003 to June 2004, during which time
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21 9 168 countries signed the treaty⁸. It provides a comprehensive strategy to combat the tobacco
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23 10 epidemic, including SLT (Appendix 5)⁹. The FCTC is WHO's first global public health treaty¹⁰. It
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25 11 is legally the international community's most powerful tobacco control instrument¹¹. The
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27 12 Convention is binding on countries through ratification, acceptance, approval, formal confirmation
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29 13 or accession¹². The WHO FCTC must be transposed into national law, applied and enforced to
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31 14 become part of the national law of a sovereign state. This includes comparing existing legislation
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33 15 with the treaty provisions, examining administrative structures and adapting them where necessary,
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35 16 and developing administrative and technical guidance for its application¹³. Currently, 182 Parties,
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37 17 whose populations represent 90% of the world's population, have signed the Convention¹⁴. Existing
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39 18 reviews of the impact of the FCTC indicate promising approaches to reducing tobacco use^{9, 15}.
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41 19 Although SLT products fall within the policy framework of the WHO FCTC, they have not
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43 20 received the same priority as tobacco among FCTC Parties. Only 34 out of 180 Parties (as of 2019)
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45 21 tax or report taxing SLT products, six Parties measure SLT product content and constituents, and
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47 22 41 of the Parties require pictorial health warnings on products. Only a few Parties collect or present
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49 23 data on smokeless tobacco use through global or national surveillance mechanisms (e.g. Global
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3 1 Tobacco Surveillance System and WHO STEPwise) or have comprehensive bans on advertising,
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5 2 promotion or sponsorship of SLT⁴.

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7 3 The WHO FCTC has been the subject of several studies, both for smoking and SLT, e.g. by Chung-
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9 4 Hall et al., Mehrotra et al., Siddiqi et al. and Gravely et al.^{4, 9, 16, 17}. These papers provide deep
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11 5 insights into the implementation of the WHO FCTC. They describe whether FCTC measures have
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13 6 been implemented at national level for SLT. However, they do not provide information on whether
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15 7 these measures have been evaluated. Furthermore, not all UN states have signed the Convention.
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17 8 Some Parties have signed the treaty but have not implemented it, e.g. the USA, Argentina, Cuba
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19 9 or Switzerland. Some Parties have not signed but ratified the Convention, e.g. Tajikistan, Bahrain
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21 10 and Zimbabwe. Other Parties have signed and ratified the Convention but do not report data to
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23 11 WHO on the status of their SLT responses (Table 1). For these countries, policy evaluation studies
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25 12 are one way to get an overview of the effectiveness of tobacco control policies. They summarise
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27 13 what data are available for which level of jurisdiction (state, county, city). This increases the
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29 14 explanatory power for the different policy instruments used depending on the underlying
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31 15 organisational structures and legal responsibilities. It provides an overview of tobacco control
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33 16 policy, which areas are covered, how target groups respond, what indirect effects (may) occur and
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35 17 what data gaps exist. Moreover, combining WHO reporting with data from sub-national levels
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37 18 (states, county, city) for countries reporting under the WHO system allows for a more detailed and
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39 19 nuanced understanding of compliance with the WHO FCTC Framework Convention in these
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41 20 countries.

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43 21 This work adds to the existing literature. The aim of the scoping review is to summarise studies
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45 22 that have analysed government policies to control SLT use in order to fill the gaps in the WHO
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47 23 FCTC reporting system. The objectives are to identify: (1) countries for which studies evaluating
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49 24 public policies are available to complement existing WHO FCTC data, and (2) the level of
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1 jurisdiction, population groups and instruments studied, and the impact on consumption behaviour
2 reported in these studies.

3 **METHODS**

4 The scoping review follows a similar approach to a systematic review¹⁸⁻²¹. The Preferred Reporting
5 Items for Systematic Reviews and Meta-Analysis: extension for Scoping Reviews (PRISMA-SCR
6 and flow chart) were used to illustrate the flow of information through the different stages of the
7 scoping review²². A study protocol was published in advance²³.

9 **Search strategy and information sources**

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

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

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3 1
45 **2 Inclusion and exclusion criteria**

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8 3 The focus was on studies that evaluated the control of SLT at each level of jurisdiction to
9
10 4 complement the knowledge collected for reporting on the implementation of WHO FCTC^{4, 9, 17}.

11
12 5 Our aim is to identify additional information to fill the gaps in reporting systems where data are
13
14 6 not available. No restrictions were placed on the language or type of study. No review articles or
15
16 7 modelling studies were included. Grey literature was not included due to lack of resources, e.g.
17
18 8 ministerial reports, reports from international or social organisations.

19
20
21 9 We screened all included studies for reported affiliation, conflict of interest and funding to control
22
23 10 for industry involvement. Only studies where the authors did not declare a conflict of interest or
24
25 11 industry funding and where the authors were not affiliated with an industrial company were
26
27 12 included.

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30
31 **13 Data extraction, coding and analyses**

32
33 14 Studies were grouped by country, jurisdiction level (national, state, county, city), WHO FCTC
34
35 15 articles and population groups studied. SLT policy effects were coded as positive, mixed or
36
37 16 negative/no effect. The positive effect could be a reduction in consumption, a reduction in
38
39 17 purchasing behaviour, knowledge of the regulations or compliance, depending on the instrument
40
41 18 or focus studied. A mixed effect was coded if the results indicated a positive and a negative effect.
42
43 19 No/negative effect was indicated if the results indicated that the policy had no effect or led to an
44
45 20 increase in SLT use, or if a negative perception of the SLT control policy was reported.

46
47
48
49 21 If available in the included articles, information was provided on why the effect may have occurred
50
51 22 or what influenced the outcome. Detailed information and the extraction sheet were published in
52
53 23 protocol²³. The extraction sheet was tested a priori. A narrative synthesis of the included studies is
54
55 24 used to interpret and analyse the data.

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6 2**RESULTS**

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9 3 A total of 1,011 articles were found in the database search and 35 articles were found in the
10
11 4 reference list check. After duplicates were removed, 925 articles were screened by title and
12
13 5 abstracts and 197 articles were included in the full text screening. The inclusion criteria were met
14
15 6 by 40 articles (Appendix 2.1 Flow chart). One article had to be excluded from the full text screening
16
17 7 due to a lack of language skills within the research team, as it was written in Japanese, and is
18
19 8 marked accordingly in the flow chart. Within the articles, Pimple et al. 2014²⁴, Ohsfeldt et al.
20
21 9 1997²⁵, McClelland et al. 2015²⁶ and Mumford et al. 2005²⁷ report on two instruments; Patja et al.
22
23 10 2009²⁸ report on two countries: Finland and Sweden, which are treated separately. Thus, the 40
24
25 11 articles refer to 41 studies. None of the full texts included reported industry involvement.
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Countries covered, policy instruments evaluated in terms of WHO FCTC articles, and level of jurisdiction

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35
36 15 The most important characteristics of the included studies are listed in appendix 2. A large number
37
38 16 of studies were conducted in the USA (n=17^{25-27, 29-42}), followed by India (n=15^{24, 43-56}) and Finland
39
40 17 (n=3^{28, 57, 58}). One study each reported results from Bhutan⁵⁹, Myanmar⁶⁰, Sweden²⁸, Bangladesh⁶¹,
41
42 18 Norway⁶² and South Africa⁶³. One study analysed different member states of the EU⁶⁴. According
43
44 19 to the World Bank 64 classification, twenty-two studies were conducted in high-income countries,
45
46 20 one in an upper-middle-income country and 18 in lower-middle-income countries. One study
47
48 21 reporting results from different EU countries is not included in the classification. Study designs
49
50 22 used were cross-sectional (n=16^{24, 30, 32, 35, 36, 40, 44, 48-52, 56, 57, 59, 60}), observational (pre-post studies
51
52 23 and interrupted time series analyses (n=5^{33, 38, 41, 55, 61}), trend analyses (n=2^{26, 42}), qualitative studies
53
54 24 (n=3^{47, 53, 64}) and mixed methods (n=2^{45, 46}). Other designs used were snowball/network designs
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1 (n=1⁴³) and quantitative designs (n=3, quasi-experimental comparison³⁹, randomised controlled
2 trial³⁴, quantitative descriptive study⁶²). Secondary data were used in nine studies, with Finland and
3 Sweden counted as separate studies in the Patel et al. article^{25, 27-29, 31, 37, 58, 63}.

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

20 Some studies that assessed national policies were less concerned with the specific instruments used,
21 but examined in general terms the control of availability, access and promotion of SLT; awareness,
22 attitudes and perceived barriers to policy implementation; application, enforcement and
23 compliance with existing national regulations; and their impact on the trends in SLT consumption²⁸.
24 ^{44, 46, 59, 60, 63}. Studies that did not mention specific instruments are marked as 'general'. Other studies

1 assessed the impact of specific policy measures, such as the impact of tax regulations on SLT
2 consumption^{25-27, 30, 33, 40, 55}, ban on gutkha and pan masala^{24, 45, 47, 48, 50, 53}, health warnings on SLT
3 packaging^{37, 43, 61}, ban on sales near educational institutions^{24, 49, 51, 52}, ban on flavoured products^{38,}
4 ^{39, 41}, smoke-free law, including analyses of litter indicating SLT use²⁵⁻²⁷ and one study each for a
5 display ban⁶², packaging and labelling issues⁵⁶, sales and advertising³², marketing and sales⁴²,
6 modified retail outlet environments³⁴, sales to minors³⁶, product availability in pharmacies³⁵,
7 banning snus⁵⁸ and snuff⁵⁷, public expenditure on tobacco control programmes in general³¹ and
8 taxes on products sold online across countries, and advertising bans within the EU⁶⁴ (Appendix 4
9 Table 4. 1 and 4.2).

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

17 **Reported effects of SLT control policies**

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

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

1
2
3 1 towards the policy as a whole. Positive effects were also reported for health warnings, taxes, the
4
5 2 ban on flavoured products, the ban on snuff and the ban on display with regard to SLT.
6
7 3 Mixed effects were reported for general aspects of the policies, health warnings, sales near
8
9 4 educational institutions, bans on gutkha/pan masala, packaging and labelling, sales and advertising,
10
11 4 educational institutions, bans on gutkha/pan masala, packaging and labelling, sales and advertising,
12
13 5 marketing and sales, changes in the outlet environment, sales to minors, product availability in
14
15 6 pharmacies and cross-country online taxes, and advertising within the EU.
16
17 7 In the included articles, no or negative impacts were reported for general aspects, health warnings,
18
19 8 bans on sales near educational institutions, bans on gutkha/pan masala, smoke-free laws and snus
20
21 9 bans (Appendix 4 Table 4.2).
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26 11 **India**

27
28 12 The general evaluation of COTPA, the health warnings (Article 11), the ban on advertising and
29
30 13 sales near educational institutions (Articles 13, 16), packaging and labelling (Article 11), the ban
31
32 14 on gutkha and pan masala, and the taxation of SLT products (Article 6) were examined.
33
34

35 15 Studies evaluating COTPA in general and analysing the impact of the implementation of the Goods
36
37 16 and Services Tax (GST) on prices and its influence on SLT consumption found positive impacts⁵⁵.
38
39

40 17 The positive impacts of COTPA evaluation were discussed in terms of the population studied. The
41
42 18 study population was older than 50 years and had more than 10 years of schooling. It was discussed
43
44 19 that the higher awareness was probably due to a medium socioeconomic status and a good
45
46 20 perception of second-hand smoke as harmful, and that higher education might be associated with
47
48 21 a positive attitude towards COTPA⁴⁴. The results, although positive, may only apply to this
49
50 22 population group.
51
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53 23 Mixed effects were reported for regulations banning guthka and pan masala. The regulations are
54
55 24 well known, but the products, especially those produced locally; continue to be available to regular
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1 customers or in the black market at a higher price^{24, 45, 47, 48, 50, 53}. Reddy et al. also reported that
2 most gutkha consumers switch to other products (29.8% of the study population) and that
3 newspapers were the main source of information about the ban (45.8% of the study population).
4 However, they also reported high literacy levels in the study population⁵⁰. Mixed effects were also
5 found for the use of health warnings. While health warning regulations are followed for cigarettes,
6 they are not followed for g gutkha⁴³.
7 No effects were found for the ban on sales near educational institutions. Although the ban is widely
8 known, it is not implemented and rarely enforced. In addition, mobile vendors sell locally and are
9 difficult to prosecute^{24, 51, 52}. Furthermore, it is rarely known that violations can be reported. Selling
10 to minors is accepted as a form of income. A study on COTPA among shopkeepers found that
11 consumption and sales to minors are accepted, including as a form of income⁴⁶. Barriers to the
12 effectiveness of interventions mentioned include a lack of comprehensive information and
13 awareness of the law, lack of economic alternatives especially for small-scale vendors, cultural
14 acceptance of tobacco use, lack of political support, and the low priority given to combating SLT
15 in general⁴⁶.

17 USA

18 In the USA, the ban on flavoured products had a positive impact on reducing SLT consumption
19 (Article 9). The ban was accompanied by an extensive pre-ban information campaign and strong
20 enforcement structures^{38, 39, 41}. In addition, positive effects were found for high spending on public
21 tobacco control programmes³¹.

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

1 education levels, with higher education levels associated with higher awareness. Awareness of
2 health warnings about SLT was lowest among those with low education and low annual household
3 income³⁷. For the sales and advertising tools, point-of-sale advertising and the use of predominant
4 tobacco advertising displays were reported to be more prevalent in shops more likely to be
5 frequented by youth. Snus was also sold to underage purchasers^{32, 36}. One study evaluated several
6 national control measures and reported positive effects on tobacco uptake, but no effects on current
7 users. It suggests a mix of tobacco control measures (higher taxes on smokeless tobacco, higher
8 minimum legal age for purchasing tobacco products, strict licensing requirements for tobacco
9 products, restrictions on giving away free samples of tobacco products, posting of signs indicating
10 the minimum age for purchasing tobacco products) would be effective in reducing SLT use among
11 adolescent males²⁹.

12 Three studies examining higher taxes on SLT use and surveying students and young adults (≥ 25)
13 reported no impact on SLT use^{26, 27, 40}. One study found an increase in SLT use among males in
14 parallel with an increase in cigarette taxes⁴⁰. Two other studies reported that a higher cigarette tax
15 was associated with a decrease in cigarette use in general, but also with a shift and product
16 switching to SLT^{25, 30}. 69% of pharmacies in Massachusetts were licensed to sell tobacco products
17 (all cigarettes, moist snuff (53%), snus (14%)). This represented 9% of licensed tobacco retailers³⁵.
18 The introduction of a tobacco-free pharmacy concept would impact the majority of pharmacies in
19 Massachusetts, as a variety of products are currently sold in licensed pharmacies.

21 **Other countries**

22 For the other countries, the picture is similarly diverse. In Finland²⁸ and South Africa⁶³, the
23 evaluation of national tobacco control policies produced positive results. Both reported a decrease
24 in SLT consumption, in South Africa even without excise tax. However, in South Africa, an

1
2
3 1 increase in consumption among black African women and a shift from the older to the youth
4
5 2 population was noted⁶³. In Norway, 98 % of shopkeepers complied with the ban on displaying
6
7 3 snus⁶².
8
9
10 4 Mixed impacts were reported for tobacco control policies in Myanmar and the online cross-country
11
12 5 evaluation of the tax and advertising ban in the EU. Awareness of the policy is high in Myanmar.
13
14 6 However, SLT products are still sold and there is a lack of awareness that non-compliance can
15
16 7 result in a fine⁶⁰. Although SLT products are banned in Finland, the prevalence of daily use among
17
18 8 women is high and SLT products can be imported for personal use²⁸. In the EU, taxation of tobacco
19
20 9 products has been introduced and there is a ban on cross-border sales. However, cross-national
21
22 10 online sales are still possible⁶⁴.
23
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29 12 **Population groups covered**

30
31 13 The results of the evaluation of national policies to combat SLT consumption are diverse, and this
32
33 14 also applies to the population groups included. The results are based on parts of the population
34
35 15 (Table 3). The included studies report results for the following subgroups: students (n=8^{26, 29, 31, 49,}
36
37 16 ^{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,
38
39 17 retail outlets (n=4^{24, 42, 43, 56}), retail tobacco outlets (n=2^{24, 42}), licensed pharmacies (n=1³⁵) and
40
41 18 school districts (n=1⁵¹). Sixteen articles did not further specify the population surveyed^{26, 27, 30, 33,}
42
43 19 ^{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
45 20 ^{44, 50, 52}. Seventeen studies did not specify gender. Gender did not play a role in the 15 studies that
46
47 21 used household data or analysed the implementation of advertising bans in outlets and shops (Table
48
49 22 3, Appendix 2).
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56 24 **(3) Gaps in SLT policy evaluation research**

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3 1 The current and comprehensive assessment of the WHO FCTC is based on the WHO Global
4
5 2 Progress Reports on FCTC Implementation 2012, 2014, 2016. 2018; WHO reports on the global
6
7 3 tobacco epidemic 2013, 2015, 2017, WHO NCI Monograph, Global Tobacco Surveillance System
8
9
10 4 Data (including results from the Global Adult Tobacco Survey, Global Youth Tobacco Survey,
11
12 5 Global Professions Student Survey, Global School Personnel Survey), country, regional and global
13
14 6 smokeless tobacco control reports, tobacco control laws and regulations, and searches of PubMed
15
16
17 7 for WHO FCTC-specific key terms. They provide a comprehensive overview of the current
18
19 8 situation and the availability of regulations and data. However, the data are highly aggregated.
20
21 9 Policy evaluation studies complement this overview by answering questions at the national or
22
23 10 regional level with a focus on the application of regulations. However, the data are sparse. Data are
24
25
26 11 only available for India, the USA, Bangladesh, Bhutan, Finland, Myanmar, South Africa, Sweden
27
28 12 and Norway. The data are also limited to Articles 6, 8, 9, 11, 13 and 16, and some of the Articles
29
30 13 are only partially covered, such as Article 13, which deals with advertising and marketing.
31
32 14 Sponsorship and advertising are not covered in the included studies. Another example is Article
33
34 15 16, which specifically prohibits the sale of SLT products near schools. Policy evaluations in India
35
36 16 found that the problem of mobile vendors and the role of disadvantaged neighbourhoods influence
37
38 17 the impact of policies on certain groups. These findings need to inform public policy making at the
39
40 18 designated legislative level. However, data are not available for every level of jurisdiction and
41
42 19 every article.
43
44 20 No national, federal, regional or municipal policy evaluation studies are available for Articles 7,
45
46 21 12, 14, 15, 17, 18, 19, 21 and 22 (Table 4).
47
48 22 Policy evaluation studies are the only data sources for the USA, as it has signed but not ratified the
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50 23 WHO FCTC and is therefore not included in the WHO FCTC data reports.
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1 DISCUSSION

2 The aim of this scoping review was to identify: (1) countries for which studies evaluating public
3 policies are available to complement existing WHO FCTC data, and (2) the level of jurisdiction,
4 population groups and instruments studied, and the impact on consumption behaviour reported in
5 these studies. Most studies have been conducted in India and the USA, which is consistent with the
6 work of Mehrotra et al.⁴ and Siddiqi et al.¹⁷. However, there is a lack of studies evaluating SLT
7 policies at national and subnational levels in countries with high SLT prevalence (e.g. Sri Lanka,
8 Nepal, Mauritania or Sudan, Norway, Croatia). Only for seven countries (Bangladesh, Bhutan,
9 Myanmar, South Africa, Finland, Sweden, Norway) we found policy assessments in addition to
10 WHO FCTC evaluations. For Articles 6, 9, 11, 13 and 16, there is overlap between the WHO FCTC
11 article evaluation reported by Mehrotra et al. and the studies identified in our work⁴. However,
12 national evaluation studies have assessed the impact of tobacco control policies using waste
13 analysis, which could be used to fill this gap²⁵⁻²⁷. In addition, not all data are available for the same
14 country and jurisdiction level, which limits the transferability of results. Except for the US and
15 India, the results are not based on different affected populations such as consumers/former
16 consumers, people in different socio-economic groups, illiterate people or retailers. This made it
17 difficult to make predictions about the acceptance and compliance of individual measures in
18 different population groups. Preliminary findings on how enforcement of the WHO FCTC might
19 affect SLT sellers in Pakistan and their attitudes towards such measures can be found in a recently
20 published paper⁶⁵. Such findings are necessary to be prepared for the direct and indirect effects that
21 the introduction of strict SLT control policies might have⁶⁶. Further studies on public policy are
22 needed that analyse the application and enforcement of control measures and the interaction
23 between international regulations and national, federal and regional responsibilities. Research is
24 needed on the impact of public policies on consumption patterns, problem awareness and behaviour

1
2
3 1 change. A recently published protocol⁶⁷ and the recent study published by Yadav et al. for India
4
5 2 begin to fill these gaps⁶⁸. Future research should also aim to analyse the role of industry
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7 3 participation in SLT public policy making.
8
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10 4 The impacts found point to some interesting facts that should be considered in the development
11
12 5 and evolution of policies to control SLT consumption and products. First, while higher taxation of
13
14 6 tobacco products is an appropriate tool to reduce prevalence and consumption of tobacco products,
15
16 7 product substitution should be considered for subgroups. Especially in countries with large local
17
18 8 production (e.g. India) or cross-border purchasing habits (e.g. Finland), more information is needed
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20 9 on the perceptions and responses of different consumer groups, as well as on the impact and
21
22 10 consequences of taxation, in order to align taxation with other instruments, such as strict licensing
23
24 11 requirements for tobacco products, the display of signs indicating the minimum age for purchasing
25
26 12 tobacco products, awareness-raising campaigns and campaigns to promote social norms and
27
28 13 education. In addition, strong public support and enforcement capacity could strengthen regulatory
29
30 14 approaches. Secondly, while policies may be widely known, external factors determine how
31
32 15 regulations are administered and adhered to. For subgroups, e.g. people of low socio-economic
33
34 16 status, lack of education, in deprived neighbourhoods, users and former users, shopkeepers and
35
36 17 people who derive their income from the production, transport and sale of SLT products, education
37
38 18 campaigns and support strategies should be discussed to promote compliance. However, to do this,
39
40 19 more detailed data are needed to inform policy action.
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46 20 Where smokeless tobacco regulation interacts with other policies, such as the regulation of 'gutkha'
47
48 21 or 'pan masala' under the Food Safety and Standards Ordinance in India, such synergies should be
49
50 22 harnessed and targeted.
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53 23 Similar to previous work, the points indicate that policies need to be adapted and developed to suit
54
55 24 the national and sub-national context. Simply transferring approaches and policy instruments may
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1 not work. While much data is available, it is fragmented, relates to different levels of jurisdiction,
2 to different target groups, and usually addresses only one aspect of control measures rather than
3 interacting systems. Data at all levels of the evidence ladder need to be combined in a meaningful
4 way to cover all level of jurisdictions. The most vulnerable groups and especially indirect effects
5 need to be considered across jurisdictions. Data on subgroups, minorities, indirect effects, high-
6 and low-income people in relation to attitudes or health warnings need to be collected and
7 combined. Evaluation data linked to the process of policy development and implementation would
8 also allow adjustments to be made if the impact does not materialise or even if it would be necessary
9 to terminate certain approaches.

12 **LIMITATION**

13 Although the work follows the systematic approach of the Joanna Briggs Institute²¹ and reports
14 according to PRISMA-ScR²², there are limitations. Due to licensing restrictions, the Embase
15 database was not included. In addition, studies published in languages other than English or
16 German were not included in the data extraction. This affected one study that was reported
17 separately in the flow chart. In addition, studies on individual interventions that do not refer to
18 public policies were not included. We may have missed some studies due to limitations to our
19 search strategy which was developed with our research librarian. For example, studies that did
20 not contain the specific search terms we used (e.g. regulation, control policy, public policy), the
21 corresponding MeSH terms or controlled vocabulary (depending on the system used in the
22 databases) in the title or abstract would not have been identified. We also did not include grey
23 literature, as this would have exceeded the resources of the research team. Work from ministries
24 and non-for-profit organisations is therefore not included as long as it has not been published in

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

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

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

12 **CONCLUSION**

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

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23 **Contribution following CRediT taxonomy of contributors**

1
2
3 1 Conceptualization, SF, ZK, HZ; Methodology, SF, ZK, HZ; Investigation, SF, ZK, AF, AF, JF,
4
5 2 TK, SU; Resources, LC; Writing original, review, editing: SF, ZK, AF, AF, JF, TK, SU, DO, KS,
6
7 3 ZH; Funding Acquisition, SF, HZ, ZK, KS.
8
9
10 4
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12

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14
15 6 None
16
17

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19
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28
29 12 publication are those of the author(s) and not necessarily those of the DAAD, NIHR or the UK
30
31 13 Department of Health and Social Care.
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37 15 **Data availability statement**

38
39 16 Not applicable. All related data are attached to the publication as appendix.
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43

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Figure captions

Figure 1: Jurisdiction covered within this scoping review

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3 **1 Tables**
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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.

1 **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

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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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