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Version: Accepted Version

Article:
Arora, Monika, Chugh, Aastha, Jain, Neha et al. (2020) Global impact of tobacco control policies on smokeless tobacco use: A systematic review protocol. BMJ Open. e042860. ISSN: 2044-6055

https://doi.org/10.1136/bmjopen-2020-042860

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Addressing Smokeless Tobacco and Building Capacity in South Asia (ASTRA) – Policy Workstream

Data Extraction Form

SECTION I: General Information and Identification		
1.	Title of the Article/ Document	
2.	Study ID *(surname of first author and year study was published e.g. Smith 2001)*	
3.	Report ID *(for projects or studies with multiple report - if different to Study ID e.g. Smith 2001_01)*	
4.	Report IDs of other reports of this study *(e.g. duplicate publications, follow-up studies)*	
5.	Date form completed (dd/mm/yyyy)	
6.	Initials of person extracting data	
7.	Full reference with URL	
8.	Type of Document	☐Scientific article ☐Government Report ☐Policy Document ☐Non-government report ☐Commentary ☐Editorial ☐Government Circular ☐Others
9.	Study author contact details	
10.	Source of document *(If ministry website, mention which ministry – Health, Environment, Commerce etc.)*	☐Academic journal ☐Ministry website, name: _____

		☐Google ☐Other, name:_____ _____
11.	Country (in which study was conducted/policy document is based)	
12.	Duration of study *(start and end date)*	
13.	State funding source	
14.	Ethics approval obtained for the study (Y/N)	

SECTION II: DETAILS OF SMOKELESS TOBACCO POLICY (specific to RQ1)

1.	Population (study participants)	☐Smokers ☐Smokeless Tobacco Users ☐Dual Users ☐Any other, please specify:
2.	Age group of study participants (adolescents/young adults/adults)	☐ All age groups ☐adults, age range: _____ ☐children/youth, age range: _____ ☐other, age range: _____ ☐comment/warning message (if any): _____
3.	Gender distribution of participants	Total number of males (%): Total number of females (%):
4.	Setting of the population ?(national or sub-national)	
5.	Number of participants/sample size	

	INTERVENTION (POLICY) DESCRIPTION	
	INTERVENTION (POLICY) 1 (replicate the entire section in case of more than 1 policy)	
1.	Intervention (policy) focus	**FCTC Policies** ☐Pricing and taxation (Article 6) ☐Product regulation (Article 9 and 10) ☐Packaging and health warnings (Article 11) ☐Education, communication, training, and public awareness (Article 12) ☐Advertisement, promotion and sponsorship bans (Article 13) ☐Cessation (Article 14) ☐Illicit trade (Article 15) ☐Sales to and by minors (Article 16) **Non-FCTC Policies** ☐Complete ban ☐Partial ban ☐Import ban ☐Other policies mentioned to control ST (agriculture, environment etc.), please specify_____
2.	Comparator *(usual care/control etc.)*	☐Reported/Describe: _____ ☐Not reported (but should be reported) ☐Not applicable
	Description of intervention (using TIDieR checklist: https://www.equator-network.org/reporting-guidelines/tidier/)	
3.	Brief name (name or phrase that describes the policy in the document)	☐Present/Describe: _____ ☐Absent (but should be reported)

		☐Not applicable (when it is legitimately not relevant)
4.	Why? (Describe any rationale, theory, or goal of the elements essential to the policy)	☐Present/Describe: _____ ☐Absent (but should be reported) ☐Not applicable (when it is legitimately not relevant)
5.	What materials (any physical or informational materials used for the policy)	☐Present/Describe: _____ ☐Absent (but should be reported) ☐Not applicable (when it is legitimately not relevant)
6.	What procedures (procedures, activities, and/or processes used in the policy)	☐Present/Describe: _____ ☐Absent (but should be reported) ☐Not applicable (when it is legitimately not relevant)
7.	Who provided (For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given; N/A for non-human provider modes)	☐Present/Describe: _____ ☐Absent (but should be reported) ☐Not applicable (when it is legitimately not relevant)
8.	How (modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group)	☐Present/Describe: _____ ☐Absent (but should be reported) ☐Not applicable (when it is legitimately not relevant)
9.	Where (Describe the type(s) of location(s) where the policy occurred, including any necessary infrastructure or relevant features)	☐Present/Describe: _____ ☐Absent (but should be reported) ☐Not applicable (when it is legitimately not relevant)
10.	When and how much (period of time covered by the policy and any specification on frequency and intensity)	☐Present/Describe: _____ ☐Absent (but should be reported) ☐Not applicable (when it is legitimately not relevant)

11.	Tailoring (If it was planned to be personalised, titrated or adapted for a specific population, then describe what, why, when, and how)	☐Present/Describe: _____ ☐Absent (but should be reported) ☐Not applicable (when it is legitimately not relevant)
12.	Modifications (any modified made to the policy during the course of the study, describe the changes (what, why, when, and how))	☐Present/Describe: _____ ☐Absent (but should be reported) ☐Not applicable (when it is legitimately not relevant)
13.	How well implemented (plan) (whether policy adherence was assessed, and if any strategies were used to maintain and improve adherence)	☐Present/Describe: _____ ☐Absent (but should be reported) ☐Not applicable (when it is legitimately not relevant)
14.	How well implemented (actual) (if policy adherence was assessed, describe the extent to which it was implemented as planned)	☐Present/Describe: _____ ☐Absent (but should be reported) ☐Not applicable (when it is legitimately not relevant)
Contextual specification of intervention		
15.	Is the extent of policy enforcement described in the document?	☐Yes, National/federal level ☐Yes, Regional/state-level/provincial ☐No If Yes, Describe the extent:_____
16.	Enforcers/regulators of the policy (Government body enforcing or regulating the policy)	☐Ministry/Department/Division of Health ☐Ministry/Department/Division of Commerce ☐Ministry/Department/Division of Finance ☐Ministry/Department/Division of Environment ☐Food and Drug Administration ☐ Others, please specify_____

17.	Does this document identify if stakeholders were involved in developing/modifying the policy?	☐Yes ☐No
18.	If Yes in Point 5, select all the stakeholders that were involved in developing/modifying the policy	☐Federal Government/National Government ☐Provincial/State/Regional Government ☐Health Care Organisations ☐Experts ☐Regulators ☐Professional Organisations (non-regulatory) ☐Clinicians ☐Patients ☐Researchers ☐Others (specify)_____ ☐Not available
19.	Does the document describe any policy drivers, e.g., preamble or rationale for introducing policies (like media coverage, political will, public health concern etc.)?	☐Yes ☐No if yes, specify details:
20.	Does the document evaluate or mention evaluation of the policy's effectiveness?	☐Evaluates impact *(complete Section III)* ☐Mentions evaluation of impact *(in methods)* *State/provide reference of the article/document with details of the impact evaluation:* ☐None of the above
21.	Any other details (limitations or other observations)	

SECTION III: DETAILS OF IMPACT OF SMOKELESS TOBACCO POLICIES (specific to RQ2)

A. Methods

			Location in text (Page #/ Figure/Table)
1.	Study objectives *(as stated in the study)*		
2.	Design	☐Randomized controlled trial ☐Controlled clinical trial ☐Cohort analytic (two groups pre+post) ☐Case-control Cross sectional (surveys) ☐Cohort (one group pre+post (before and after)) ☐Interrupted time series ☐Other specify_____ ☐Not specified	
3.	Sampling technique with details	☐Random sampling ☐Purposive sampling ☐Snowball sampling ☐Cluster sampling ☐Any other, please specify: _____ ☐Not specified	

4.	Is the analysis of the study conducted at individual level?	☐No ☐Yes, please give details:_____	
5.	Is the analysis of the study conducted at group level?	☐No ☐Yes, please give details:_____	

B. Outcomes

			Location in text (Page #/ Figure/Table)
	PRIMARY OUTCOME 1 (replicate the section in case of more than one PRIMARY outcome)		
1.	Outcome name (e.g. quit rate)		
2.	Outcome definition		
3.	Time points measured		
4.	Time since policy implementation		
5.	Time points reported		

6.	Total N (% - *at this stage of follow-up as % of N at time of enrolment in study)*		
7.	N (%) with outcome		
8.	Effect estimate *(e.g. Odds Ratio/Prevalence percentage/risk ratio/mean/median)*		
9.	Unit of effect estimate *(e.g. O*dds Ratio, percentage, mean etc.*)*		
10	Confidence/precision intervals of effect estimate *(e.g. 95% CI, IQR, SD, SR etc.)*		
11	Is tool validated for population of interest		
	INTERMEDIATE OUTCOME		
	Details		
	UNINTENDED OUTCOME		
	Details		

	Notes:

C. COMPARATORS

			Location in text (Page #/ Figure/Table)
	COMPARATOR 1 (Replicate the section in case of more than one comparator)		
1.	Comparator Name (e.g. quit rate)		
2.	Comparator definition		
3.	Time points measured		
4.	Time since policy implementation		
5.	Time points reported		
6.	Total N (% - *at this stage of follow-up as % of N at time of enrolment in study)*		
7.	N (%) with outcome		
8.	Effect estimate *(e.g. Odds Ratio/Prevalence percentage/risk ratio/mean/median)*		

9.	Unit of effect estimate *(e.g. O*dds Ratio, percentage, mean etc.*)*		
10.	Confidence/precision intervals of effect estimate *(e.g. 95% CI, IQR, SD, SR etc.)*		

D. Limitation and Mitigation Strategy (author identified)

			Location in text (Page #/ Figure/Table)
1.	Strength		
2.	Limitation		

E. Conclusions

			Location in text (Page #/ Figure/Table)
1.	Key Conclusion of Study Author/s		

F. Risk of bias (quality assessment)

1. **SELECTION BIAS**	
a. Are the individuals selected to participate in the study likely to be representative of the target population?	☐Very likely ☐Somewhat likely ☐Not likely ☐Can't tell
b. What percentage of selected individuals agreed to participate?	☐80-100% agreement ☐60-79% agreement ☐Less than 60% agreement ☐Not applicable ☐Can't tell
Rate this section (selection bias)	☐1 Strong ☐2 Moderate ☐3 Weak
2. **STUDY DESIGN**	
a. Indicate the study design	☐Randomized controlled trial ☐Controlled clinical trial ☐Cohort analytic (two groups pre+post) ☐Case-control Cross sectional (surveys) ☐Cohort (one group pre+post (before and after)) ☐Interrupted time series ☐Other specify_____ ☐Can't tell
b. Was the study described as randomized? (If No, go to component 3)	☐No ☐Yes

c. If yes, was the method of randomization described?	☐No ☐Yes
d. If yes, was the method appropriate?	☐No ☐Yes
Rate this section (study design)	☐1 Strong ☐2 Moderate ☐3 Weak
3. **CONFOUNDERS**	
a. Were there important differences between groups prior to intervention?	☐Yes ☐No ☐Can't tell
The following are examples of confounders	☐Race ☐Sex ☐Marital status/family ☐Age ☐SES (income or class) ☐Education ☐Health status ☐Pre-intervention score on outcome measure
b. If yes, indicate the percentage of relevant confounders that were controlled (either in the design (e.g., stratification, matching) or analysis)?	☐80-100% (most) ☐60-79% (some) ☐Less than 60% (few or none) ☐Can't tell
Rate this section	☐1 Strong ☐2 Moderate ☐3 Weak
4. BLINDING	
a. Was (were) the outcome assessor(s) aware of the intervention or exposure status of participants?	☐Yes ☐No ☐Can't tell

b. Were the study participants aware of the research question?	☐Yes ☐No ☐Can't tell
Rate this section	☐1 Strong ☐2 Moderate ☐3 Weak
5. DATA COLLECTION METHODS	
a. Were data collection tools shown to be valid?	☐Yes ☐No ☐Can't tell
b. Were data collection tools shown to be reliable?	☐Yes ☐No ☐Can't tell
Rate this section	☐1 Strong ☐2 Moderate ☐3 Weak
6. WITHDRAWALS AND DROP-OUTS	
a. Were withdrawals and drop-outs reported in terms of numbers and/or reasons per group	☐Yes ☐No ☐Can't tell ☐Not applicable (i.e. one time surveys or interviews)
b. Indicate the percentage of participants completing the study (if the percentage differs by groups, record the lowest)	☐80-100% ☐60-79% ☐Less than 60% ☐Can't tell
Rate this section	☐1 Strong ☐2 Moderate ☐3 Weak
7. INTERVENTION INTEGRITY	

a. What percentage of participants received the allocated intervention or exposure of interest?	☐80-100% ☐60-79% ☐Less than 60% ☐Can't tell
b. Was the consistency of the intervention measured?	☐Yes ☐No ☐Can't tell
c. Is it likely that subjects received an unintended intervention (contamination or co-intervention) that may influence the results	☐Yes ☐No ☐Can't tell
8. ANALYSES	
a. Indicate the unit of allocation (select one)	☐Community ☐Organisation/institution ☐Practice/office ☐Individual
b. Indicate the unit of analysis (select one)	☐Community ☐Organisation/institution ☐Practice/office ☐Individual
c. Are the statistical methods appropriate for the study design?	☐Yes ☐No ☐Can't tell
d. Is the analysis performed by intervention allocation status (i.e. intention to treat) rather than the actual intervention received?	☐Yes ☐No ☐Can't tell
COMPONENT RATINGS	
a. Selection Bias	☐1 Strong ☐2 Moderate ☐3 Weak
b. Study Design	☐1 Strong

	☐2 Moderate ☐3 Weak
1 Confounders	☐1 Strong ☐2 Moderate ☐3 Weak
2 Blinding	☐1 Strong ☐2 Moderate ☐3 Weak
3 Data collection method	☐1 Strong ☐2 Moderate ☐3 Weak
4 Withdrawals and drop-outs	☐1 Strong ☐2 Moderate ☐3 Weak
GLOBAL RATING FOR THIS PAPER (SELECT ONE)	☐1 Strong ☐2 Moderate ☐3 Weak
(With both reviewers discussing the ratings) Is there a discrepancy between the reviewers with respect to the component (a. – f.)	☐No ☐Yes
If yes, indicate the reason for discrepancy	☐Oversight ☐Differences in interpretation of criteria ☐Differences in interpretation of study
Final Decision of both reviewers (select one)	☐1 Strong ☐2 Moderate ☐3 Weak