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

| | | |
|-----|---|--|
| | | <input type="checkbox"/> Google <input type="checkbox"/> Other, name: _____ _____ |
| 11. | Country (in which study was conducted/policy document is based) | |
| 12. | Duration of study (<i>start and end date</i>) | |
| 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) | <input type="checkbox"/> Smokers <input type="checkbox"/> Smokeless Tobacco Users <input type="checkbox"/> Dual Users <input type="checkbox"/> Any other, please specify: |
| 2. | Age group of study participants (adolescents/young adults/adults) | <input type="checkbox"/> All age groups <input type="checkbox"/> adults, age range: _____ <input type="checkbox"/> children/youth, age range: _____ <input type="checkbox"/> other, age range: _____ <input type="checkbox"/> 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 | <p>FCTC Policies</p> <p><input type="checkbox"/> Pricing and taxation (Article 6)</p> <p><input type="checkbox"/> Product regulation (Article 9 and 10)</p> <p><input type="checkbox"/> Packaging and health warnings (Article 11)</p> <p><input type="checkbox"/> Education, communication, training, and public awareness (Article 12)</p> <p><input type="checkbox"/> Advertisement, promotion and sponsorship bans (Article 13)</p> <p><input type="checkbox"/> Cessation (Article 14)</p> <p><input type="checkbox"/> Illicit trade (Article 15)</p> <p><input type="checkbox"/> Sales to and by minors (Article 16)</p> <p>Non-FCTC Policies</p> <p><input type="checkbox"/> Complete ban</p> <p><input type="checkbox"/> Partial ban</p> <p><input type="checkbox"/> Import ban</p> <p><input type="checkbox"/> Other policies mentioned to control ST (agriculture, environment etc.), please specify _____</p> <p>_____</p> |
| 2. | Comparator (<i>usual care/control etc.</i>) | <p><input type="checkbox"/> Reported/Describe: _____</p> <p><input type="checkbox"/> Not reported (but should be reported)</p> <p><input type="checkbox"/> Not applicable</p> |
| 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) | <p><input type="checkbox"/> Present/Describe: _____</p> <p><input type="checkbox"/> Absent (but should be reported)</p> |

| | | |
|-----|---|--|
| | | <input type="checkbox"/> Not applicable (when it is legitimately not relevant) |
| 4. | Why? (Describe any rationale, theory, or goal of the elements essential to the policy) | <input type="checkbox"/> Present/Describe: <hr/> <input type="checkbox"/> Absent (but should be reported) <input type="checkbox"/> Not applicable (when it is legitimately not relevant) |
| 5. | What materials (any physical or informational materials used for the policy) | <input type="checkbox"/> Present/Describe: <hr/> <input type="checkbox"/> Absent (but should be reported) <input type="checkbox"/> Not applicable (when it is legitimately not relevant) |
| 6. | What procedures (procedures, activities, and/or processes used in the policy) | <input type="checkbox"/> Present/Describe: <hr/> <input type="checkbox"/> Absent (but should be reported) <input type="checkbox"/> 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) | <input type="checkbox"/> Present/Describe: <hr/> <input type="checkbox"/> Absent (but should be reported) <input type="checkbox"/> 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) | <input type="checkbox"/> Present/Describe: <hr/> <input type="checkbox"/> Absent (but should be reported) <input type="checkbox"/> 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) | <input type="checkbox"/> Present/Describe: <hr/> <input type="checkbox"/> Absent (but should be reported) <input type="checkbox"/> 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) | <input type="checkbox"/> Present/Describe: <hr/> <input type="checkbox"/> Absent (but should be reported) <input type="checkbox"/> 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) | <input type="checkbox"/> Present/Describe: <hr/> <input type="checkbox"/> Absent (but should be reported) <input type="checkbox"/> 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)) | <input type="checkbox"/> Present/Describe: <hr/> <input type="checkbox"/> Absent (but should be reported) <input type="checkbox"/> 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) | <input type="checkbox"/> Present/Describe: <hr/> <input type="checkbox"/> Absent (but should be reported) <input type="checkbox"/> 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) | <input type="checkbox"/> Present/Describe: <hr/> <input type="checkbox"/> Absent (but should be reported) <input type="checkbox"/> Not applicable (when it is legitimately not relevant) |
| Contextual specification of intervention | | |
| 15. | Is the extent of policy enforcement described in the document? | <input type="checkbox"/> Yes, National/federal level <input type="checkbox"/> Yes, Regional/state-level/provincial <input type="checkbox"/> No If Yes, Describe the extent: _____ |
| 16. | Enforcers/regulators of the policy (Government body enforcing or regulating the policy) | <input type="checkbox"/> Ministry/Department/Division of Health <input type="checkbox"/> Ministry/Department/Division of Commerce <input type="checkbox"/> Ministry/Department/Division of Finance <input type="checkbox"/> Ministry/Department/Division of Environment <input type="checkbox"/> Food and Drug Administration <input type="checkbox"/> Others, please specify _____ _____ |

| | | |
|-----|--|--|
| | | |
| 17. | Does this document identify if stakeholders were involved in developing/modifying the policy? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 18. | If Yes in Point 5, select all the stakeholders that were involved in developing/modifying the policy | <input type="checkbox"/> Federal Government/National Government <input type="checkbox"/> Provincial/State/Regional Government <input type="checkbox"/> Health Care Organisations <input type="checkbox"/> Experts <input type="checkbox"/> Regulators <input type="checkbox"/> Professional Organisations (non-regulatory) <input type="checkbox"/> Clinicians <input type="checkbox"/> Patients <input type="checkbox"/> Researchers <input type="checkbox"/> Others (specify) _____ <input type="checkbox"/> 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.)? | <input type="checkbox"/> Yes <input type="checkbox"/> No if yes, specify details: |
| 20. | Does the document evaluate or mention evaluation of the policy's effectiveness? | <input type="checkbox"/> Evaluates impact (<i>complete Section III</i>) <input type="checkbox"/> Mentions evaluation of impact (<i>in methods</i>) <i>State/provide reference of the article/document with details of the impact evaluation:</i> <input type="checkbox"/> 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 <i>(as stated in the study)</i> | | |
| 2. | Design | <input type="checkbox"/> Randomized controlled trial <input type="checkbox"/> Controlled clinical trial <input type="checkbox"/> Cohort analytic (two groups pre+post) <input type="checkbox"/> Case-control Cross sectional (surveys) <input type="checkbox"/> Cohort (one group pre+post (before and after)) <input type="checkbox"/> Interrupted time series <input type="checkbox"/> Other specify _____ <input type="checkbox"/> Not specified | |
| 3. | Sampling technique with details | <input type="checkbox"/> Random sampling <input type="checkbox"/> Purposive sampling <input type="checkbox"/> Snowball sampling <input type="checkbox"/> Cluster sampling <input type="checkbox"/> Any other, please specify: _____ <input type="checkbox"/> Not specified | |

| | | | |
|----|---|---|--|
| 4. | Is the analysis of the study conducted at individual level? | <input type="checkbox"/> No <input type="checkbox"/> Yes, please give details: _____ | |
| 5. | Is the analysis of the study conducted at group level? | <input type="checkbox"/> No <input type="checkbox"/> 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 (% - <i>at this stage of follow-up as % of N at time of enrolment in study</i>) | | |
| 7. | N (%) with outcome | | |
| 8. | Effect estimate (<i>e.g. Odds Ratio/Prevalence percentage/risk ratio/mean/median</i>) | | |
| 9. | Unit of effect estimate (<i>e.g. Odds Ratio, percentage, mean etc.</i>) | | |
| 10 | Confidence/precision intervals of effect estimate (<i>e.g. 95% CI, IQR, SD, SR etc.</i>) | | |
| 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 (% - <i>at this stage of follow-up as % of N at time of enrolment in study</i>) | | |
| 7. | N (%) with outcome | | |
| 8. | Effect estimate (<i>e.g. Odds Ratio/Prevalence percentage/risk ratio/mean/median</i>) | | |

| | | | |
|-----|--|--|--|
| 9. | Unit of effect estimate (<i>e.g. Odds Ratio, percentage, mean etc.</i>) | | |
| 10. | Confidence/precision intervals of effect estimate (<i>e.g. 95% CI, IQR, SD, SR etc.</i>) | | |

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? | <input type="checkbox"/> Very likely <input type="checkbox"/> Somewhat likely <input type="checkbox"/> Not likely <input type="checkbox"/> Can't tell |
| b. What percentage of selected individuals agreed to participate? | <input type="checkbox"/> 80-100% agreement <input type="checkbox"/> 60-79% agreement <input type="checkbox"/> Less than 60% agreement <input type="checkbox"/> Not applicable <input type="checkbox"/> Can't tell |
| Rate this section (selection bias) | <input type="checkbox"/> 1 Strong <input type="checkbox"/> 2 Moderate <input type="checkbox"/> 3 Weak |
| 2. STUDY DESIGN | |
| a. Indicate the study design | <input type="checkbox"/> Randomized controlled trial <input type="checkbox"/> Controlled clinical trial <input type="checkbox"/> Cohort analytic (two groups pre+post) <input type="checkbox"/> Case-control Cross sectional (surveys) <input type="checkbox"/> Cohort (one group pre+post (before and after)) <input type="checkbox"/> Interrupted time series <input type="checkbox"/> Other specify _____ <input type="checkbox"/> Can't tell |
| b. Was the study described as randomized? (If No, go to component 3) | <input type="checkbox"/> No <input type="checkbox"/> Yes |

| | |
|--|---|
| c. If yes, was the method of randomization described? | <input type="checkbox"/> No <input type="checkbox"/> Yes |
| d. If yes, was the method appropriate? | <input type="checkbox"/> No <input type="checkbox"/> Yes |
| Rate this section (study design) | <input type="checkbox"/> 1 Strong <input type="checkbox"/> 2 Moderate <input type="checkbox"/> 3 Weak |
| 3. CONFOUNDERS | |
| a. Were there important differences between groups prior to intervention? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't tell |
| The following are examples of confounders | <input type="checkbox"/> Race <input type="checkbox"/> Sex <input type="checkbox"/> Marital status/family <input type="checkbox"/> Age <input type="checkbox"/> SES (income or class) <input type="checkbox"/> Education <input type="checkbox"/> Health status <input type="checkbox"/> 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)? | <input type="checkbox"/> 80-100% (most) <input type="checkbox"/> 60-79% (some) <input type="checkbox"/> Less than 60% (few or none) <input type="checkbox"/> Can't tell |
| Rate this section | <input type="checkbox"/> 1 Strong <input type="checkbox"/> 2 Moderate <input type="checkbox"/> 3 Weak |
| 4. BLINDING | |
| a. Was (were) the outcome assessor(s) aware of the intervention or exposure status of participants? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't tell |

| | |
|--|---|
| b. Were the study participants aware of the research question? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't tell |
| Rate this section | <input type="checkbox"/> 1 Strong <input type="checkbox"/> 2 Moderate <input type="checkbox"/> 3 Weak |
| 5. DATA COLLECTION METHODS | |
| a. Were data collection tools shown to be valid? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't tell |
| b. Were data collection tools shown to be reliable? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't tell |
| Rate this section | <input type="checkbox"/> 1 Strong <input type="checkbox"/> 2 Moderate <input type="checkbox"/> 3 Weak |
| 6. WITHDRAWALS AND DROP-OUTS | |
| a. Were withdrawals and drop-outs reported in terms of numbers and/or reasons per group | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't tell <input type="checkbox"/> 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) | <input type="checkbox"/> 80-100% <input type="checkbox"/> 60-79% <input type="checkbox"/> Less than 60% <input type="checkbox"/> Can't tell |
| Rate this section | <input type="checkbox"/> 1 Strong <input type="checkbox"/> 2 Moderate <input type="checkbox"/> 3 Weak |
| 7. INTERVENTION INTEGRITY | |

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

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